Exhibit 75

The relationship between perineal cosmetic talc usage and ovarian talc particle burden

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OBJECTIVE: Epidemiologic studies support the hypothesis of a dose-related risk of epithelial ovarian cancer with perineal talc exposure. Frequency and duration of talc usage has not been previously correlated with ovarian talc content.
STUDY DESIGN: Ovaries were studied from 24 women undergoing incidental oophorectomy who were interviewed regarding talc usage. Twelve subjects reported frequent perineal talc applications; the twelve controls reported no use. Ovarian tissue blocks were digested and analyzed by polarized light microscopy and analytic electron microscopy to identify and quantify talc.
RESULTS: Talc was identified in all 24 cases by either light or electron microscopy. Talc particle counts were completely unrelated to reported levels of perineal talc exposure.
CONCLUSIONS: The detection of talc in all ovaries demonstrates that it can reach the upper genital tract. Widespread exposure to talc during diapering may contribute to the ubiquitous presence of talc in ovarian tissue. (Am J Obstet Gynecol 1996;174:1507-10.)

Key words: Talc, ovary

Epidemiologic evidence suggests that perineal exposure to talc is associated with an increased risk of epithelial ovarian cancer in a dose-related fashion.[1-5] Other epidemiologic studies have shown no increased risk of ovarian cancer associated with talc.[6, 7] Studies show access of particulate matter into the female peritoneal cavity through the transvaginal route.[8-10] A few reports have identified talc in ovarian tissue,[11, 12] both benign and malignant, but these data were not correlated with an exposure history. Other potential genital tract exposures in a woman's life include surgical gloves,[13] condoms, and diaphragms. Diapering with talc during infancy is another potential exposure. Epidemiologic studies have not linked these exposures to an increased risk of ovarian cancer.[1, 2]

If transvaginal transport of perineally applied talc occurs, women with the heaviest exposures may show the largest talc particle burdens in their ovaries. Tissue digestion techniques are an accepted analytic adjunct in the identification and quantification of asbestos in the lungs of occupationally exposed individuals[14, 15] and are useful in the identification and quantification of talc as well. The goal of this pathoepidemiologic study was to correlate the history of perineal talc usage with the talc particle burden found in the ovaries.

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Material and methods

In a case control study of benign ovarian neoplasms at Columbia Presbyterian Medical Center, women undergoing surgery from 1992 to 1993 were interviewed regarding various factors, including talc usage. Subjects were also questioned regarding possible occupational exposures to asbestos, and mothers were contacted regarding diapering history whenever feasible.

Subjects were categorized for talc exposures as follows. Women who reported no direct application of talc to the perineum or to underwear were considered unexposed. For women who reported talc application to underwear or the perineum, the total number of lifetime applications was estimated as the average frequency of use times the number of years of use. For instance, a woman who reported perineal talc application twice per day for 10 years was considered to have 7240 applications. To simplify the classification of exposed and unexposed women, subjects who reported tubal ligation, diaphragm use, or feminine hygiene spray use were excluded from this analysis.

Interviewed subjects from the parent case control study who had a normal contralateral ovary in the surgical specimen were eligible for this substudy. Sections of normal ovary from the 12 women who reported the largest number of perineal talc applications were analyzed. For each of these subjects the unexposed woman closest in age was selected as a control. In addition, the ovaries of two stillborn fetuses were analyzed as negative controls.

Table I. Talc particle counts in women who reported perineal cosmetic talc usage

Subject No.	*age (yr)*	*Lifetime talc applications**	*EM talc particle counts†*	*Polarized light microscopic counts†*	*Asbestos detected*	*Talc use with diapering*
1	49	4,784	1,600,288	96	No	Yes
2	49	5,475	0	54	No	Unknown
3	57	6,552	0	100	Yes	No
4	31	8,144	0	114	No	Unknown
5	43	10,556	0	464	Yes	Unknown
6	45	11,284	151,300	300	No	Yes
7	50	11,648	236,406	345	No	Yes
8	57	15,600	0	75	No	Yes
9	66	18,980	0	250	Yes	Yes
10	47	21,840	1,576,000	111	No	Unknown
11	44	23,660	0	348	No	Yes
12	44	39,312	7,565,000	26	Yes	Unknown

EM, Electron microscopy.
*Frequency of use × Years of use.
†Per gram wet tissue weight.

Ovarian tissue in blocks was deparaffinized, rehydrated, blotted dry, and weighed. Digestion with 5% potassium hydroxide was performed at 70° C for 2 to 4 hours. After complete digestion, the tissue was centrifuged at 12,000 revolutions/min for 20 minutes. The potassium hydroxide was removed, leaving a pellet to which approximately 20 ml of distilled water was added. The pellet was resuspended by use of a microultrasonic cell disrupter at 50 W for 5 seconds. Centrifugation, distilled water wash, and microultrasonic cell disrupter were repeated three times. The distilled water was removed, and the pellet was resuspended in 5 to 10 ml of distilled water. Drops of 10 μl of the final suspension were placed on nickel formvar and carbon-coated locator grids and air-dried. Transmission electron microscopy to identify particles and their size was performed. The identity of the particles was determined by energy-dispersive spectroscopy and confirmed by electron diffraction. Grids were viewed at both 10,000 and 19,000 diameters. All talc particles observed were counted. Cytospin slides for polarized light microscopy were prepared from the same final suspension as the electron microscopy grids. Polarized light microscopy counted larger talc particles (limits of detection approximately 1 μm), whereas electron microscopy detected smaller ones (limits of detection approximately 0.5 nm).

Routinely, all solutions are checked for detectable limits of contaminating particles; all places where particles could have contaminated the specimen, such as paraffin, are also controlled for.

Associations between talc exposure and talc particle count in the 12 exposed subjects were assessed with Spearman's rank correlation coefficient.

Results

Detailed results can be seen in Tables I and II. The mean age of the patients was 49 years (range 29 to 66 years). For eight exposed subjects, a control was found who was within 4 years of her age. Talc particle counts were not related to age in either the exposed or unexposed subjects ($p > 0.25$). The mean number of lifetime exposures for the women reporting perineal talc use was 14,820 (range 4784 to 39,312). Talc was detected in all ovaries by either polarized light or electron microscopy. There was a wide range of values, as shown by the large SDs. Table III shows that talc particles were observed to a similar extent with both exposed and unexposed subjects.

Neither the light microscopic nor electron microscopic values correlated with reported perineal talc usage (p values 0.37 and 0.45). There was a negative correlation between the values obtained by light microscopy and electron microscopy ($r = -0.34$, $p = 0.05$). An attempt to contact mothers of subjects was successful for 11 of the 24 subjects. Ten of these reported using talc to diaper their babies, which indicates that lifetime talc exposure may be underestimated for nearly all the subjects. Analyses of two fetal ovaries and a pair of surgical gloves was completely negative for talc.

In one subject we studied both ovaries; on the right side we detected no talc by electron microscopy and 556 particles by light microscopy, and on the left side we detected 1,669,000 particles per gram of wet weight by electron microscopy and 6 particles by light microscopy. Hematoxylin-eosin stained slides from the analyzed sections of tissue were examined. There was no evidence of response to talc, such as foreign body giant cell reactions or fibrosis in the tissue. Asbestos was detected in ovaries of five of the subjects with no talc exposure and in four ovaries of the talc-exposed subjects.

Comment

If transvaginal transport of perineally applied talc occurs, we would expect women with the heaviest exposures to show the largest talc particle burden in their ovaries.

Table II. Talc particle counts in women without history of perineal cosmetic talc usage

Subject No.	*Age (yr)*	*Reported exposure history*	*EM talc particle count**	*Polarized light microscopic talc particle counts**	*Asbestos detected*	*Talc use with diapering*
1	63	0	1,350,000	89	No	Yes
2	57	0	315,250	111	No	Yes
3	29	0	0	42	No	Unknown
4	48	0	1,669,000	6	Yes	Unknown
5	59	0	315,208	166	Yes	Yes
6	40	0	0	69	Yes	Yes
7	43	0	0	566	Yes	Unknown
8	64	0	0	420	Yes	Yes
9	49	0	0	53	No	Unknown
10	54	0	0	1139	No	Unknown
11	32	0	63,042	2200	No	Unknown
12	58	0	472,813	0	No	Unknown

EM, Electron microscopy.
*Per gram wet tissue weight.

Table III. Comparison of particle burdens between reported exposed and nonexposed subjects

Talc exposure	*No. of subjects with talc by EM*	*No. of subjects with talc by light microscopy*	*Mean EM particle count**	*SD*	*Mean light microscopic particle count**	*SD*
Reported talc use ($n = 12$)	5/12	12/12	927,416	2,174,888	190	144
No reported talc use ($n = 12$)	6/12	11/12	348,776	570,055	405	655

EM, Electron microscopy.
*Per gram wet tissue weight.

Tissue digestion techniques have been used to identify and quantify particle burdens of various organic materials in human tissue. The most notable use of this technique is in the identification of asbestos in the lungs of occupationally exposed individuals.[14, 15] Other studies have examined other organs as well. In the 1979 report of Henderson et al.[11] ovaries were studied after an oxygen incineration procedure. They found 6900 to 55,100 talc particles per gram of wet weight in three normal ovaries, 17,400 to 24,300 in three cystic ovaries, and 6400 to 24,500 in three ovarian adenocarcinomas. No exposure histories were stated.

Our study attempted to correlate ovarian talc particle burden with exposure history. Our results do not support a linear dose-related ovarian talc particle burden. However, the mean electron microscopic particle count was much higher in talc users. Perhaps perineal talc does contribute to the ovarian particle burden; however, factors other than dosage may contribute. Other factors to consider include method of application, type of talc, and the possible contribution of inhaled talc particles. The range of talc particle values obtained in this study was wide, as evidenced by the large SDs. This spread of values was also present in the study of Henderson et al.[11] and in much of the asbestos fiber burden literature. Talc may be unevenly distributed throughout the ovarian parenchyma. This is supported by the discrepant counts we obtained on the one subject who had analysis of both ovaries. The lack of correspondence between polarized light and electron microscopy counts was due to measurement of different size particles.

Undocumented exposures to talc may partly explain the lack of correlation between adult histories of perineal cosmetic talc applications and ovarian burdens. Although both examination and surgical gloves in the past were dusted with talc, we cannot document this exposure. The gloves we currently use are talc free, according to the company and to our analyses. Ten of the 11 available mothers reported using talc while diapering their babies; this ubiquitous exposure may also contribute to the ovarian particle burdens.

Talc as a possible etiologic agent in the development of epithelial ovarian cancer may be related to asbestos exposure in several ways. Aside from the chemical similarities between the two, many cosmetic talcs contained significant amounts of asbestos, particularly before 1976.[1] Although tremolite asbestos has been documented as a containment of some talc preparations, the types of asbestos detected here are more commonly associated with an environmental (chrysotile) or occupational (chrysotile and crocidolite) exposure.[16]

The detection of talc in all the ovaries demonstrates

that talc can reach the upper genital tract. However, the quantity detected in this study did not correlate well with the reported exposure. Further study is required to elucidate whether the presence of talc in ovarian tissue is pathogenic.

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Exhibit 76

Presence of Talc in Pelvic Lymph Nodes of a Woman With Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc

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BACKGROUND: Although epidemiologic studies suggest talc use may increase ovarian cancer risk, there is no proof that talc used externally reaches the pelvis.

CASE: A 68-year-old woman with stage III ovarian papillary serous carcinoma revealed she had used talc daily for 30 years to powder her genital area. Examination of her pelvic lymph nodes under polarized light microscopy showed diffuse areas of birefringence compatible with talc, confirmed by scanning electron microscopy and X-ray spectroscopy.

CONCLUSION: This description of talc in pelvic lymph nodes of a woman with ovarian cancer and decades of exposure to talc may prompt new studies and offer new insights into the biologic basis for the consistent, but debated, association between talc use and ovarian cancer.
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An epidemiologic association between the use of cosmetic talc in genital hygiene and ovarian cancer was first described in 1982, and many subsequent studies found talc use to increase risk for ovarian cancer.[1] However, the causality of the relationship has been challenged for several reasons.[2] First, the association is a relatively weak one (ie, summary relative risk of approximately 1.3). Second, no clear increase in risk with duration of use has been found in most studies. Third, the ability of talc used in the genital area to enter the pelvic cavity has not been conclusively proven. At the time of pelvic surgery for ovarian cancer, pelvic lymph nodes are commonly sampled for staging purposes, but pathologic examination of the nodes is focused on the presence or absence of metastatic disease. More careful examination of pelvic lymph nodes from women with ovarian cancer may contribute to new perspectives in the debate regarding the role of talc in the causation of ovarian cancer, as illustrated by the following case.

CASE

A 68-year-old, married woman presented with abdominal swelling. A computed tomographic scan revealed a 13-cm pelvic mass, and her serum CA 125 level was more than 1,000. She was referred to the Gynecologic Oncology Service at the Brigham and Women's Hospital, where cytoreductive surgery was performed, including total abdominal hysterectomy, bilateral salpingo-oophorectomy, omentectomy, and pelvic lymph node sampling. A stage III papillary serous carcinoma with a minor clear cell component was found. Metastatic serous carcinoma was described in two of six right external iliac and obturator nodes. Postoperatively, the patient was referred for chemotherapy. She also consented to our interview about risk factors for ovarian cancer. This study is approved by the Dana Farber–Harvard Cancer Center Institutional Review Board and permits administration of general and dietary questionnaires, blood donation, and investigation of surgical specimen(s) after written informed consent. The patient's past history included three term deliveries followed by a tubal ligation. She had not smoked, used oral contraceptives, or used postmenopausal hormone therapy other than 6 months of progesterone therapy to regulate periods around the time of menopause, which occurred at age 50. There is a family history of colon cancer in a sister and maternal grandmother. At our interview, the patient stated she had used talc daily for 30 years as a body powder on the perineum and also applied it to underwear and sanitary napkins.

In searching for ideas to help clarify the association between talc use and ovarian cancer, we consulted with an expert on mesothelioma (J.G.), who pointed out that asbestos and other particulate material commonly migrates to lymph nodes.[3,4] We decided that a more systematic examination of pelvic lymph nodes from ovarian cancer cases might be in order, beginning with this case. In examining the patient's pelvic lymph nodes, no distinct particulates were seen under regular light microscopy, although a diffuse histocytic reaction was noted, even in a node without metastases (Fig. 1A). Under polarized light, diffuse

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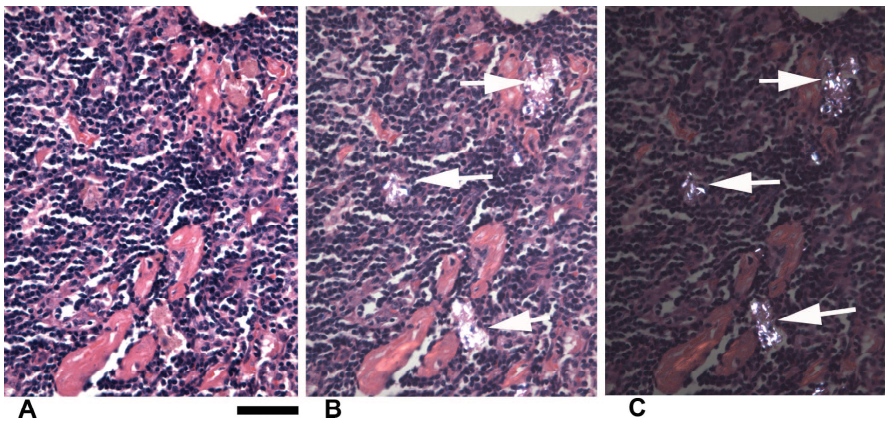

Fig. 1. Hematoxylin and eosin–stained section of a lymph node from the case showing morphologic findings with no polarization of the microscope light and with combinations of polarized and incident light at several different levels. **A.** Nodal morphology is illustrated and reveals no particulates seen without polarized light, but clusters of histiocytes are more prominent than usual. **B.** This panel shows the same field with polarized light plus additional light to view tissue context; birefringence is noted especially in areas of histiocyte clusters. *Arrows* are used to call attention to the birefringent particles. **C.** This shows the same field without added light, revealing the particulate nature of the birefringent material. *Arrows* highlight the particulate. Magnification bar shows 100 μm and applies to all three panels.

Cramer. Talc in Pelvic Lymph Nodes. Obstet Gynecol 2007.

birefringence was seen corresponding to the areas of histiocyte infiltration (Fig. 1B). Figure 1C shows the same field under polarization with no added light, revealing the particulate nature of the material, compatible with talc. Three of this patient's four nodes (not containing metastases) displayed polarizing material. Using methods described by Shelburne et al,[5] we next examined lymph nodes from this patient by combined scanning electron microscopy and energy dispersive X-ray spectroscopy. Scanning electron microscopy revealed plate-like particulates in the 5–10 μm range within the lymph node, in which energy dispersive X-ray spectroscopy showed a magnesium and silicate signature—compatible with talc (Fig. 2A,B). Dystrophic calcium deposits were also found within her nodes, probably a consequence of nodal aging. Of nodes from the next 12 patients examined, this case was strongest for birefringence; but these nodes have not yet been subjected to scanning electron microscopy or energy dispersive X-ray spectroscopy. Figure 3 illustrates a node negative for polarization (or histiocyte reaction) from a patient with ovarian cancer who had not used talc.

COMMENT

Talc is a hydrous magnesium silicate chemically similar to asbestos but structurally quite different. Asbestos has a fiber-like structure and talc a plate-like one. Because of this difference, it has been argued that the relationship between asbestos and mesothelioma should not be invoked to explain how talc might cause ovarian cancer. However, one feature of expo-

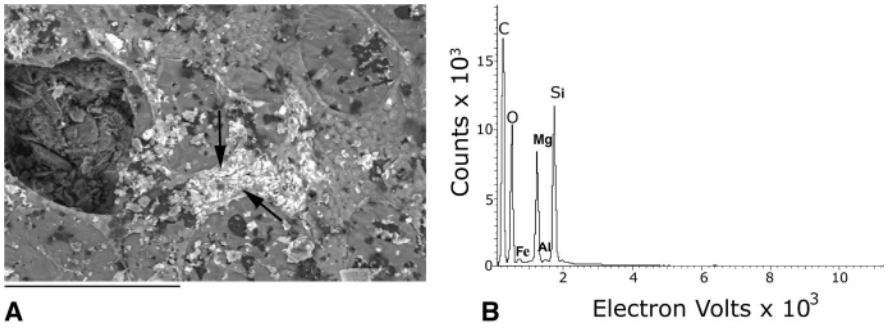

Fig. 2. Analytical microscopy. **A.** Scanning electron microscopy of a histologic section of the lymph node from the case shows a large collection of plate-like particulates in the 5–10 μm range *(arrows)* as well as scattered individual particulates. Magnification bar shows 100 μm. **B.** X-ray spectrum taken from the central bright area with particles reveals a Magnesium (Mg), Silicon (Si), and Oxygen (O) signature compatible with talc. A Carbon (C) signal is coming from the tissue or the underlying Carbon plancette or both.

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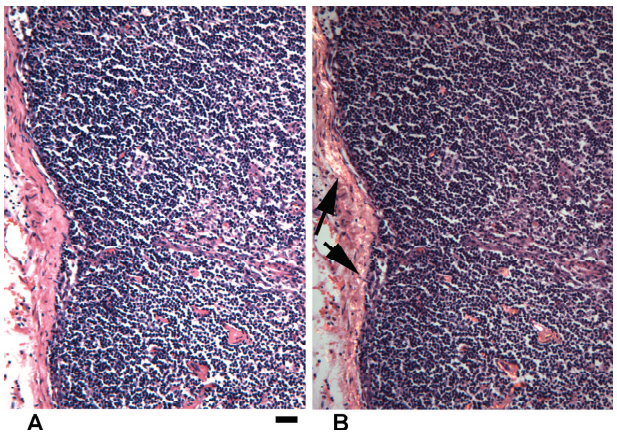

Fig. 3. Comparative node section illustrated from a woman reporting no talc use. **A.** Hematoxylin and eosin stained section showing fewer macrophages than seen in the node in Figure 1A. Magnification bar shows 100 μm. **B.** Polarized light examination of the same area of the node showing only some birefringence in the node capsule *(arrows)* compatible with collagen.

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sure that the minerals do have in common is nodal dissemination. Migration and entrapment in lymph nodes is observed in human asbestos exposure and correlates with the asbestos burden.[3] Talc has also been described in pulmonary lymph nodes of talc miners.[4] However, a MEDLINE search of (all language) publications between January 1950 and February 2007 using the search terms, "talc," "birefringence," "histiocytosis," "lymph nodes," and "ovarian neoplasms," revealed no reports of talc in lymph nodes of ovarian cancer patients.

In one of the few studies in women to evaluate the potential for talc to migrate into the pelvis, Heller et al studied normal ovaries from women having oophorectomy for benign disease.[6] The protocol involved a multistep process of tissue rehydration, blotting, drying, digestion, rehydration, centrifugation, and multiple washes. After this process, polarizing bodies were found in all ovarian specimens examined by light microscopy. By electron microscopy, tissues from 5 of 12 women who regularly used talc and 6 of 12 who had not were found to have particles consistent with talc. The investigators concluded that talc can be found in ovaries but that this does not correlate with genital talc use. Contamination that might have been introduced during extensive processing is a potential weakness of this study.

In this case report, we describe examination of pelvic lymph nodes from a woman with ovarian cancer who had been a long-term talc user. Particles compatible with talc were clearly visible under polarized light in regular hematoxylin and eosin–stained sections from her pelvic nodes, which were then shown by scanning electron microscopy and energy dispersive X-ray spectroscopy to be talc. Thus, as opposed to the aforementioned study, we focused on pelvic lymph nodes rather than ovaries; and talc was shown to be present in macrophages within the actual tissue, ruling out contamination during processing.

In reporting this case, we are not proposing that pelvic lymph nodes from women with ovarian cancer must now be subjected to electron microscopy. However, pathologists may wish to examine pelvic lymph nodes with evidence of histiocytic infiltrates by polarized light microscopy. Clear evidence of polarization may be reported so that clinicians can obtain information about potential talc exposure, if this information has not already been collected. Also we are not claiming that a causal relationship between ovarian cancer and talc use is proven for this case or in general. Because case reports cannot establish causality, we have begun a more extensive study of nodes with two purposes. First it is necessary to establish in a quantitative manner the likelihood of finding talc in lymph nodes of women with ovarian cancer and correlate this by whether they did or did not use talc. Second, studies of immune markers in nodes may help make the case for a causal connection.

What we do hope this case report accomplishes is to infuse a fresh perspective on the talc and ovarian cancer association. Previous biologic arguments linking talc and ovarian cancer have been based upon: similarities between talc and asbestos, the ability of talc to reach the ovaries through the open female tract, and induction of a mesothelioma-like cancer from the ovarian epithelium. Our new perspective would not depend upon structural similarities between talc and asbestos. The adverse effects of talc may relate to its ability to induce an inflammatory reaction, a well-established property of talc, independent of any similarity to asbestos.[7] Also, we don't believe that talc needs to reach the ovaries to affect ovarian cancer risk; rather, the harmful effects of talc may involve inflammatory reactions in the lower genital tract, including the upper vagina, cervix, and endometrium. These tissues express the surface glycoprotein human mucin 1, MUC1, whose function is to protect cells from environmental stressors. It is likely that chronic talc exposure is one factor that upregulates MUC1 expression. Human mucin 1 is related to CA 125 (MUC16), and like CA 125 is overexpressed in ovarian cancer. It is known that women with ovarian cancer who have anti-MUC1 antibodies survive longer, leading us to propose that

many risk factors for ovarian cancer may be explained by their ability to raise or lower MUC1 immunity.[8] Looking at predictors of anti-MUC1 antibodies, talc use was a factor that lowered anti-MUC1 antibodies. Thus, rather than a direct carcinogenic effect on ovarian epithelium, immune dysregulation involving MUC1 may be induced by chronic talc use that may lower protective immunity. Furthermore, sequestration of talc in nodes may affect antigen processing and be another important element in the postulated immune dysregulation.

In conclusion, this description of talc in pelvic lymph nodes of a long-term talc user with ovarian cancer may begin to reshape understanding about the relationship between talc and ovarian cancer and shed new light on whether talc used externally in the genital area is capable of migrating into the pelvis.

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Postpartum Sudden Death From Pulmonary Hypertension in the Setting of Portal Hypertension

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BACKGROUND: Pulmonary arterial hypertension carries a high maternal mortality rate in the peripartum period. Pulmonary hypertension may arise as a complication of portal hypertension with poor patient survival.

CASE: A young primigravida with chronic autoimmune hepatitis and portal hypertension presented at 26 4/7 weeks of gestation with contractions and bleeding. Within 48 hours, an 892-g female fetus was delivered vaginally without complications. On postpartum day 2, the mother was found on the floor by her bed. Although initially responsive, within minutes she was unresponsive and resuscitation was unsuccessful. Postmortem examination showed cirrhosis and plexogenic pulmonary arteriopathy.

CONCLUSION: Increased awareness of pulmonary hypertension as a complication of portal hypertension and a high index of clinical suspicion are necessary to diagnose pregnant women with this condition and provide appropriate prenatal counseling and peripartum intervention.

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Pulmonary hypertension is an under-recognized complication of portal hypertension. We present an individual with known autoimmune hepatitis with cirrhosis and portal hypertension where underlying pulmonary hypertension was identified after her postpartum sudden death. Pulmonary hypertension may present in a subtle manner, but is important to appreciate in this high-risk obstetric patient population.

CASE

A young primigravida with a 10-year history of autoimmune hepatitis with chronic thrombocytopenia presented to the hospital at 26 4/7 weeks of gestation with contractions and bleeding. Before her pregnancy, she was a noncompliant transplantation candidate not using birth control. Prenatal care had been initiated at 6 weeks of

Exhibit 77

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Correlative polarizing light and scanning electron microscopy for the assessment of talc in pelvic region lymph nodes

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ABSTRACT

Perineal talc use is associated with ovarian carcinoma in many case-control studies. Such talc may migrate to pelvic organs and regional lymph nodes, with both clinical and legal significance. Our goal was to differentiate talc in pelvic lymph nodes due to exposure, versus contamination with talc in the laboratory. We studied 22 lymph nodes from ovarian tumor patients, some of which had documented talc exposure, to quantify talc using digestion of tissue taken from paraffin blocks and scanning electron microscopy/energy dispersive X-ray analysis (SEM/EDX). Talc particles correlated significantly with surface contamination assessments using polarized light microscopy. After adjusting for surface contamination, talc burdens in nodes correlated strongly with perineal talc use. In a separate group of lymph nodes, birefringent particles within the same plane of focus as the tissues in histological sections were highly correlated with talc particles within the tissue by *in situ* SEM/EDX ($r = 0.80$; $p < 0.0001$). We conclude that since talc can be a surface contaminant from tissue collection/preparation, digestion measurements may be influenced by contamination. Instead, because they preserve anatomic landmarks and permit identification of particles in cells and tissues, polarized light microscopy and *in situ* SEM/EDX are recommended to assess talc in lymph nodes.

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Introduction

In diseases related to foreign particulate exposure, accurate quantification of foreign material in tissue is important to document exposure and to correlate with disease occurrence or severity related to that tissue.[1] The issue is perhaps best appreciated for asbestos and pulmonary mesothelioma and fibrosis.[2] The most comprehensive quantification is obtained by digestion of a tissue sample, which uses much larger amounts of tissue that can be assessed in a histologic tissue section.[1] The procedure can be used to identify and quantify individual fibers by transmission electron microscopy (TEM) or scanning electron microscopy (SEM) and characterize them by energy dispersive x-ray analysis (EDX) to verify that their elemental signatures are compatible with a specific type of asbestos or other foreign material exposure[3] Application of TEM and/or SEM and EDX to tissue sections cut from paraffin blocks also provides quantification when the concentration of particles in tissue is sufficiently high.[4,5] This procedure may also show where the foreign material resides within a tissue section, such as exogenous particles localizing in macrophages within lymph nodes.[6] An estimate of foreign particulate exposure may also be obtained by studying histologic tissue sections under polarized light microscopy, which highlights birefringent material and its size and shape.[7,8] Besides the use of these methods in scientific studies to characterize exposures and disease, these techniques have also been used in medicolegal contexts related to claims of injury from various exposures, including asbestos.[1]

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One exposure of great current medical, public health, and medicolegal importance is the association of ovarian cancers with the use of talc cosmetic products in the genital area. Data related to this association come from epidemiologic studies which identified a clear excess of women with ovarian malignancy who had used talc in their genital area prior to developing cancer, compared to control women.[9–13] The International Agency for Research on Cancer has declared the use of talc (not containing asbestos) in the genital area as possibly carcinogenic (Class 2B) (IARC monograph, 2010).[14] The most recent summary of the epidemiologic data in 2018 found that genital talc use may increase the risk for ovarian carcinoma by about 30%.[15] Although the origin of the hypothesis about talc and ovarian cancer came, in part, from description of talc in ovarian tissue,[16] demonstration that talc is present in the ovarian tissue or the genital tract from women with ovarian cancer has not been a component of the epidemiologic studies, and published data regarding talc in women's pelvic organs is very limited. A study by Heller et al.[17] was done with digestion techniques followed by TEM on ovaries from 24 women having hysterectomy/oophorectomy for reasons other than ovarian malignancy. This study found talc in approximately half the samples, with no obvious correlation with genital talc use history, thereby suggesting to the authors that talc exposure may be relatively ubiquitous across the population. A subset of authors from the present study have previously described a case report[6] in which a woman with serous carcinoma of the ovary, and a history of talc usage in her genital area, was demonstrated to have talc in three of four examined pelvic lymph nodes.

In the study reported here, we assessed talc in a sizable set of lymph nodes of the pelvic region, representing multiple patients. Thus, we expanded on the lymph node analysis in the previous case report[6] as well as the study of non-malignant ovaries by Heller et al.[17] and we examined nodes in 22 patients with various types of ovarian tumors. We included the additional step of an independent polarized light microscopy study on the histological sections for each case; this procedure assessed the quantity and location of birefringent particles in relationship to tissue landmarks. By digesting the lymph node samples, assessing the presence of talc by SEM/EDX, and comparing that data to the findings by light microscopy, we assessed tissue surface contamination as a factor explaining the high talc burden in some cases, as opposed to talc that migrated to the nodes from perineal exposure. We also endeavored, by studying a separate group of lymph node cases, to show that polarized light microscopy is a useful adjunct to *in situ* SEM/EDX, since both preserve anatomic landmarks and can serve as indicators of talc whose source is not due to contamination.

Materials and methods

Twenty-two women with ovarian tumors who had received their care in 2004 and 2005 at the Brigham and Women's Hospital (BWH), and who had participated in larger epidemiologic studies of ovarian cancer in Eastern Massachusetts and New Hampshire, were selected for the study. Women in this series were selected consecutively on the basis of meeting eligibility criteria and not on the basis of whether they had used talc. To be eligible, cases must have had lymph nodes removed from the pelvic region as part of their surgery. Cases were ineligible if the only nodes available contained metastatic disease or if there was only one unaffected node available. Though most of the cases were malignant ovarian neoplasms, two cases (one a borderline tumor and the second a granulosa cell tumor) were included because the study's objective was focused on the quantification of talc in tissue and understanding contamination vs. exposure related findings. Relevant clinical data were available both from the medical record and questionnaires completed by the women that included information on the use of talc in the genital area or as a body powder. The study was approved by the BWH Institutional Review Board and the informed consent signed by the women included permission to study material removed at the time of surgery. This group of women had both digestion studies and light microscopic studies of their lymph nodes. For our purposes, nodes of interest included inguinal, iliac, and paraaortic, and potentially any node of the pelvic region used for sampling and/or staging in ovarian surgical oncology. In some cases, the

designation "pelvic lymph node" with laterality, but without further anatomic specification, was provided with a sample.

Talc is readily visible under polarizing light microscopy, where it may be found as both plates and fibrous forms, and where the particles or fibers are brightly birefringent and often in the size range 1–10 μm. Identification of talc by electron microscopy and energy-dispersive X-ray analysis (EDX), includes the plate-like particulate or fiber-like structure and a spectrum showing magnesium and silicon peaks within 5% of the theoretical atomic ratio of 0.75 and atomic weight percent ratio of 0.649.

For each patient case, we ascertained that an acceptable representative hematoxylin-eosin (H&E)-stained slide was available for the block prior to subsequent steps. Tissue was totally cut from the paraffin block with a cleaned scalpel, heat deparaffinized, and then multiple extractions were done with xylene to remove all residual paraffin. The tissue was weighed, then added to glass centrifuge tubes, and sodium hypochlorite solution was added for digestion over a 24–48 hr period. When digestion was complete, samples were centrifuged and the sediment resuspended in filtered distilled water and vortexed until no sediment was visible. The tubes were centrifuged again and the supernatant aspirated. Sediments were resuspended in 25% ethanol, mixed by vortexing and filtered through a 13 mm, 0.2 μm Millipore filter. Tubes were washed twice with 25% ethanol and filtered. Filters were dried in a desiccator and were mounted on a carbon planchette.

Samples were analyzed in a scanning electron microscope (Leo 1460VP) equipped with an EDX spectrometer (Oxford instruments with Inca software) or an Hitachi SU6600 field emission scanning electron microscope with Oxford EDX (Xmax 50SDD EDX detector) and Oxford instrumentation software (Aztec 3.3). At 2000x magnification, 200 particles or 100 random fields were analyzed for each case, whichever came first. Using various parameters, including the number of talc particles identified by their chemical composition, the area of each microscopic field times the number of fields examined, and the overall filter area, an estimate for the total number of talc particles in the specimen was calculated.

Because fat, fibrous tissue, and lymph node contributed to the weight of the material used for digestion and because there were differences in birefringent particle distribution patterns of the tissue surface, fat and fibrous tissue, and lymph node, a more accurate approach was needed by which we could estimate the contributions of the separate locations. Tissues on all slides were digitized. Using NIH Image J analysis software (an open source image processing program, www.imagej.com), the total areas (cm^2) of the tissue on the slides for each case were calculated, as well as the respective components of lymph node and fibroadipose (soft) tissue, with the sum of these areas adding up to the total tissue area. These figures were then multiplied by 0.25 cm (a typical thickness for tissue in paraffin cassettes from which the digested tissues were derived) to obtain total specimen volumes for the total tissue, and for the lymph node and soft tissue components. The total number of talc particles identified in the digestate by SEM was then divided by the total tissue volume to obtain the number of talc particles per unit volume (cm^3).

H&E slides of intact lymph node tissue corresponding to each digested paraffin sample were analyzed with an Olympus BH-2 light microscope equipped with polarizing filter capabilities (analyzer and rotating polarizer with specimen slide in between). Each slide was scanned systematically and completely at 200x magnification under polarized light. Slides typically contained one to several lymph node profiles with adherent fibroadipose tissue. Birefringent particles visually consistent with talc (typically 1–10 μm with birefringence) were counted that were located within the lymph node parenchyma and sinuses, and a separate count was made of particles in fibroadipose (soft) tissue, i.e. not within the lymph nodes proper. The counts of these two components were added to get the total count. Particles within fibroadipose tissue were counted only if they were at least one 400x (high-power) field away from the surface, so that obvious surface contamination was not included in the counts. The birefringent particles present within lymph nodes were taken to indicate clinically significant talc that migrated there through the lymphatic system. Birefringent particles on the physical surface of the tissues were not counted for these analyses but instead assessed as described below.

Using the aforementioned image analysis data which provided the areas (cm^2) for the total tissue on the slide as well as the lymph node and soft tissue components, for each slide, the respective tissue volumes were calculated by multiplying the areas by 4 μm (4×10^{-4} cm), a standard tissue section thickness on glass slides. The number of birefringent particles per unit volume were then calculated (through simple division) for each tissue component and for the overall tissue. This meant that the volume correction factor between tissue blocks and tissue slides was approximately 625 (0.25 cm thickness of tissue in blocks vs. 4 μm thickness of slides).

Additionally, for each of the 22 cases, a semi-quantitative visual estimate of surface contamination was made. This was done by observing the quantity and pattern of all polarizable material (typically birefringent particles of 1–10 μm, plus larger material such as paper, organic fibers, and other debris) that were present along the specimen edge and/or within one 400x (high power microscopic field) width from it. The objective here was to measure the degree to which the specimen surfaces might have been contaminated by physical manipulation during the acquisition and handling steps of the specimen in the Pathology department. Our estimate scores ranged from 0 to 3 and the criteria for the scoring was as follows (see Figure 1): 0, no polarizable material along surface; 1, occasional foreign particulates, rarely forming small clusters; 2, moderate numbers of surface particulates, forming occasional clusters or surface patches more numerous than in score 1; 3, frequent patches of particulates along with confluent stretches of contamination along the surface. Typically, such contamination was seen along the fibroadipose tissue surface with the nodal tissue interior to that. The contamination consisted typically of a mix of larger debris consistent with paper, along with smaller birefringent particulates similar to those seen and described in tissue sections (Figure 1). All contamination scores were done by a pathologist (JJG) in a blinded fashion (SEM and clinical data were unavailable at the time of scoring). A randomly chosen subset of the same cases was independently scored by a second pathologist (SM), also in a blinded fashion, to confirm successfully that the review standards agreed, and thus the scoring standards were being applied consistently.

Subsequent statistical analysis for the 22 cases was handled as follows: Talc counts were log transformed to create normal distributions. Spearman correlations were calculated to assess the relationship between potential contamination on the talc counts and each continuous variable, and partial correlations were used to examine the relationships between talc counts, adjusted for contamination. Linear regression was used to calculate crude and contamination-adjusted talc/total volume geometric means and 95% confidence intervals.

Also, as part of this report, we studied a second group of 19 lymph node specimens from 10 ovarian carcinoma cases. The 10 cases were consults of authors JJG and WW, which were de-identified, i.e. reported here without any patient identifiers, including the 18 recognized HIPAA identifiers.[18] All 19 tissue specimens had histologic slides and corresponding paraffin blocks available. In this component of the study, we assessed the relationship of the numbers of birefringent particles in the lymph node parenchyma in histological sections, and talc particles found by *in situ* SEM/EDX at deeper levels in the tissue blocks corresponding to those sections. Digestion was not performed on these cases; nor was information available on their talc exposure. Birefringent particles in the lymph nodes were exhaustively quantified by light microscopy as previously described (particles counted in respective lymph node and soft tissue components, added to a total count for each slide). The histologic slides typically contained from one to several lymph node profiles, each with adherent fibroadipose tissue. Counting was done without regard to the number of profiles; i.e. an aggregate count was obtained across all lymph node tissue on a slide.

The tissue blocks were handled with a procedure for *in situ* SEM/EDX distinct from the tissue digestion and filter analysis by SEM described in the previous component of the study. This *in situ* procedure was first described by Thakral and Abraham[4] for assessment of particulate materials in paraffin-embedded tissue. In the study reported here, the blocks were handled with particle-free gloves on pre-cleaned surfaces and sectioned removing ~30 micrometers of tissue

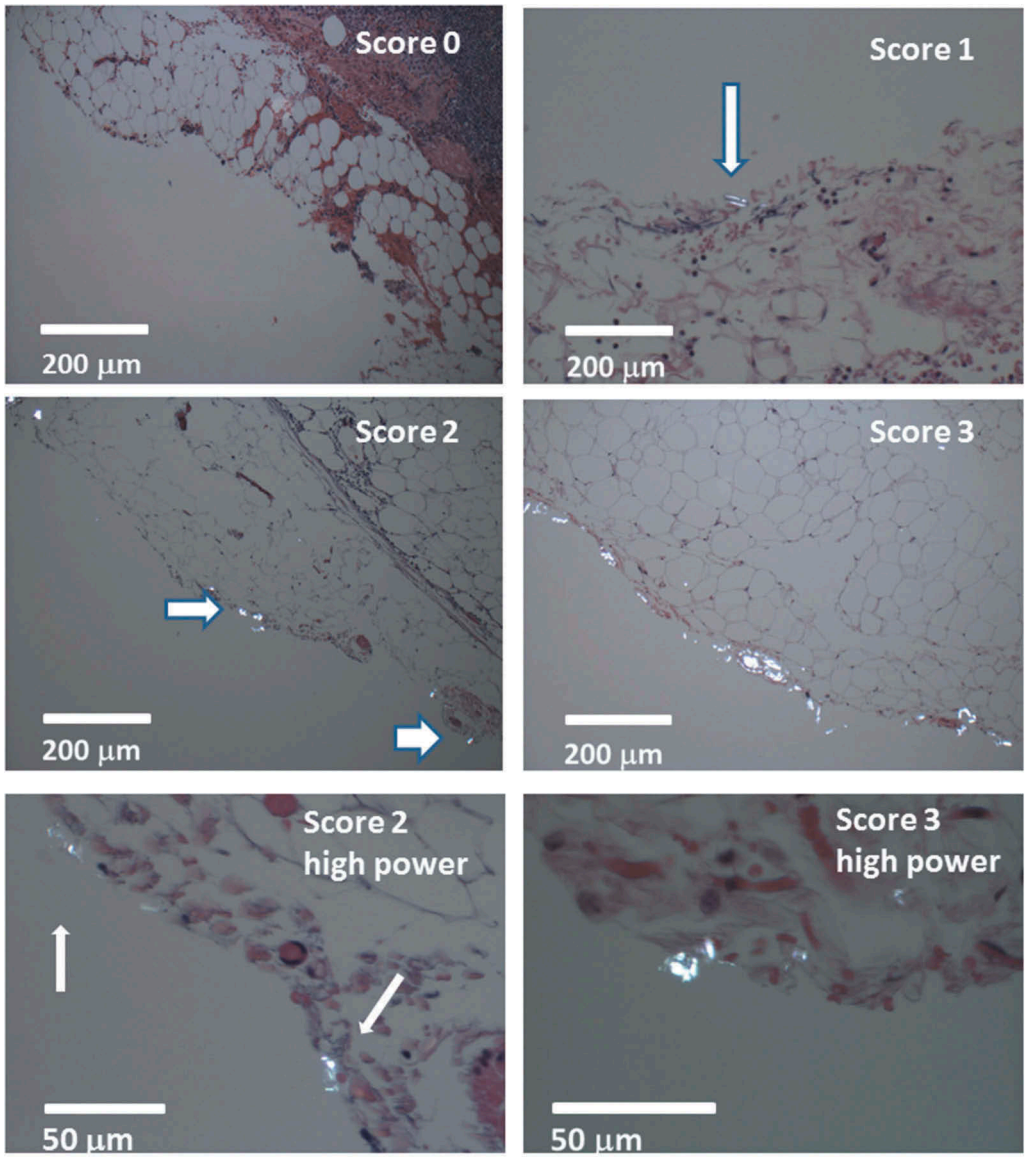

Figure 1. Tissue surface contamination score semi-quantitative grading. As shown especially in the two high-power images at bottom, the contamination material consisted typically of larger debris consistent with paper, along with smaller birefringent particulates. Surface contamination was typically found along the fibroadipose tissue surface, with lymph node tissue located underneath. Grading scheme is as follows: **Score 0**: no polarizable material along surface. **Score 1**: occasional birefringent particulates (arrows), rarely forming small clusters. **Score 2**: moderate numbers of surface birefringent particulates (arrows), forming occasional clusters or surface patches more numerous than in score 1. **Score 3**: frequent patches of particulates along with confluent stretches of contamination along the surface. (All images under polarizing light microscopy, H&E staining, all 100x except 400x [original magnification] in the bottom two images which respectively show score 2 and 3).

and paraffin using a rotary microtome with a new, clean stainless-steel blade. This sectioning was intended to remove any surface contamination from previous storage and handling. After the fresh surface was exposed, the block surfaces were washed in distilled, deionized water for 30 seconds to remove soluble surface materials such as sodium chloride and sodium phosphates used in processing for histology. The blocks were mounted for SEM examination and always kept in closed containers to limit any lab contamination. These tissue surfaces were studied with a Hitachi SU6600 field emission SEM with an Oxford EDX with Aztec version 2.0 to 3.3 software, and EDX detector model X-Max 50 SDD. The backscatter mode of the microscope highlighted mineral particles within the tissues. Areas of the tissue at the sectioned block surface were

examined at relatively low magnification 200-500x, and when particles were seen, they were then examined at higher magnification for morphological characteristics and to carry out spectral analysis on each particle found. Electron beam penetration depth under the conditions used was estimated to be 2.5 μm, with an analysis range of 0.5–2.5 μm. Of note, under *in situ* SEM the interior tissue and exterior tissue surfaces were readily distinguishable; this distinction was important for our study. In particular, as subsequent discussion will show, it was important to avoid analyzing surface particulates and instead analyze those inside the tissue. Having a scanned photocopy of the light microscopic slide and the block surface available for reference when performing SEM/EDX helped in navigating the anatomic landmarks, including surface vs. tissue interior location. We subsequently carried out an auxiliary part of this study, in which surface contamination of tissue slides was assessed using two of the cases that had this finding. The surface particles were assessed by *in situ* SEM/EDX to determine the identity (i.e. chemical composition) of the surface contamination.

For this second part of the study, linear regression analyses, with the generation of a coefficient of determination (r) goodness-of-fit value, were done between three statistical pairings: total birefringent particles by light microscopy vs. *in situ* SEM/EDX talc counts, lymph node birefringent particles vs. *in situ* SEM/EDX talc count, and fibroadipose tissue birefringent particles vs. *in situ* SEM/EDX talc counts. Our hypothesis was that the first two pairings would be correlated but the last one would not. The inclusion of multiple specimens from some of the patients meant that the 19 data points (specimens) were not truly independent of each other from the perspective of the population. However, from a statistical point of view, this was justified because, in this phase of our study, the purpose was an evaluation of methods and data related to the samples themselves, and not the population from which the samples were drawn.

Results

Digestion study

Table 1 shows characteristics of the 22 subjects enrolled in the BWH node digestion study, arrayed (least to greatest) by the amount of talc (by digestion) per cm^3 tissue volume. Fourteen (64%) of the women had invasive serous ovarian carcinoma of the ovary, which in one case was mixed with endometrioid carcinoma. Nineteen of the 22 nodes (86%) were external iliac, with 11/19 (58%) from the right side. The age range of the women was 38–73 with a median of 56; 10 (45%) had used talc in their genital area and 16 (73%) had used it as a body powder. There was considerable variation in total talc counts seen after digestion of the nodes. There was also considerable variation in birefringent particle counts in the nodal components, as well as corresponding counts per cm^3 tissue volume (see column totals where pertinent). The number and proportion of nodes with 0, 1, 2, and 3 surface contamination scores were: 4(18%), 7(32%), 7(32%), and 4 (18%).

Of note, cases 4, 9, and 13 had no clinical exposure history, and yet all had high contamination scores (either 2 or 3) and corresponding moderate to high talc counts per cm^3 tissue volume, thus highlighting a role for contamination in their digestion results. In contrast, cases 10 and 18 had clinical **exposure, but** zero contamination scores (i.e. no visible surface contamination); they also had significant talc counts per cm^3 tissue volume, indicating that in the absence of surface contamination, clinical exposure yields significant talc counts using digestion. Case 18 can also be contrasted with cases 19–22, which had the four highest talc counts per cm^3 tissue volume (Table 1), and all of which had high levels of surface contamination.

Table 2 shows Pearson and partial correlations among the various quantitative measurements related to talc and birefringent particles. The degree of surface contamination (0–3 score) as it correlates with other measures of talc and birefringent particles within the node is shown in the right-most column. The surface contamination score was significantly correlated with: the total talc particle count by digestion ($r = 0.43$, $p = 0.05$); with birefringent particle counts by light microscopy in the soft tissue (fibroadipose) component ($r = 0.53$, $p = 0.01$); with total talc per cm^3 tissue volume by SEM/EDX ($r = 0.57$, $p = 0.006$); and with birefringent particle counts in fibroadipose tissue per cm^3 fibroadipose volume ($r = 0.51$, $p = 0.01$). The remainder of correlations and p values in Table 2 represent those for partial correlations

Table 1. Clinical data and talc digestion and light microscopic data among the first patient group (BWH cases).

Case number	Tumor histology	Node*	Component volume (cm^3)			Age	Talc use		Total talc †	Talc/cm^3 of tissue volume	Total birefringence counts††			Birefringence per component volume (particles/ cm^3)			Surface contamination
			Total	Node	Fat		Genital	Body			Total	Node	Fat	Total	Node	Fat	
1	Endometrioid	REI	0.341	0.195 (57%)	0.146 (43%)	60	No	Yes	844	2,475	3750	1250	2500	11,000	6,375	17,250	1
2	Serous invasive	LP	0.334	0.171 (51%)	0.164 (49%)	53	No	Yes	1608	4,800	1250	625	625	3,737	3,661	3,812	1
3	Serous invasive	LEI	0.308	0.119 (39%)	0.188 (61%)	69	No	Yes	2065	6,705	10625	6250	4375	34,552	52,301	23,271	0
4	Serous invasive	LEI	0.407	0.252 (62%)	0.155 (38%)	38	No	No	4290	10,540	4375	1250	3125	11,187	4,960	20,187	2
5	Clear cell	REI	0.332	0.189 (57%)	0.143 (43%)	54	No	Yes	3965	11,942	15000	12500	2500	45,146	66,286	17,406	0
6	Serous invasive	REI	0.232	0.169 (73%)	0.063 (27%)	50	Yes	No	3378	14,500	1250	625	625	5,387	3,687	9,937	1
7	Endometrioid	REI	0.557	0.392 (70%)	0.165 (30%)	46	No	No	8920	16,000	4375	1250	3125	7,912	3,187	18,937	1
8	Serous invasive	LEI	0.107	0.039 (36%)	0.069 (64%)	49	Yes	Yes	2533	23,562	1250	0	1250	11,687	0	18,375	1
9	Endometrioid	REI	0.533	0.089 (17%)	0.444 (83%)	57	No	No	19,094	35,823	15000	3125	11875	28,103	35,014	26,715	2
10	Granulosa cell	REI	0.237	0.206 (87%)	0.030 (13%)	49	Yes	Yes	20,267	85,600	4,375	3,125	1,250	18,500	15,125	41,375	0
11	Serous invasive	REI	0.107	0.092 (86%)	0.015 (14%)	51	No	No	10,390	97,100	5,000	625	4,375	46,750	6,812	291,687	2
12	Serous invasive	RP	0.026	0.021 (79%)	0.006 (21%)	51	Yes	Yes	2,834	107,300	10,625	5,625	5,000	402,437	269,125	908,750	2
13	Serous invasive	LEI	0.147	0.022 (15%)	0.125 (85%)	68	No	No	16,057	115,030	16,875	1,250	15,625	114,812	56,562	125,125	3
14	Serous invasive	REI	0.219	0.145 (66%)	0.074 (34%)	73	Yes	Yes	30,330	138,500	8,125	1,875	6,250	37,062	12,937	84,437	2
15	Endometrioid	REI	0.506	0.083 (16%)	0.423 (84%)	58	Yes	Yes	73,267	144,800	26,875	12,500	14,375	53,125	151,500	33,937	2
16	Serous borderline	REI	0.147	0.055 (37%)	0.092 (63%)	60	No	Yes	21,409	145,600	11,875	2,500	9,375	80,812	45,437	101,875	1
17	Serous invasive	LEI	0.174	0.123 (71%)	0.051 (29%)	62	Yes	Yes	33,778	194,100	30,625	28,125	2,500	176,000	228,687	49,437	1
18	Serous invasive	LEI	0.323	0.203 (63%)	0.121 (37%)	53	Yes	Yes	67,557	208,200	>125,000	>125,000	625	>387,000	>616,365	3,000	0
19	Serous invasive	LEI	0.052	0.017 (33%)	0.035 (67%)	69	No	Yes	12,661	242,100	11,250	1,250	10,000	215,000	71,875	285,625	3
20	Serous invasive	LEI	0.286	0.185 (65%)	0.101 (35%)	66	Yes	Yes	92,891	325,200	4,375	3,125	1,250	15,312	16,875	12,437	2
21	Endometrioid	REI	0.056	0.039 (70%)	0.017 (30%)	51	No	Yes	85,041	1,518,589	13,750	1,250	12,500	246,875	32,051	735,294	3
22	Serous/ endometrioid	RPA	0.424	0.284 (67%)	0.139 (33%)	69	Yes	Yes	797,171	1,881,500	>62,500	>62,500	1,250	>147,500	>220,062	9,000	3
Median			0.262	0.134	0.111	56			14,359	102,200	10,625	2,188	3,125	41,104	33,533	24,993	

*Location of Node: LEI = Left external iliac; REI = Right external iliac; RPA = Right paraaortic; LP = Left pelvic; RP = Right pelvic

†Total number of talc particles by digestion (calculated)

††Total birefringence counts = particles in field x 625 (see Materials and Methods)

Node refers to lymph node parenchyma areas as measured by Image J software and studied by light microscopy (see Materials and Methods).

Fat refers to fibroadipose soft tissue areas as measured by Image J software and studied by light microscopy

Table 2. Correlations between surface contamination, talc, and age (r and p values).

Variable*	Surface contamination r (p)	Total talc by digestion r (p)	Total birefringent particle counts			Talc/total volume r (p)	Birefringent particle counts per cm^3 volume		
			Total r (p)	Node r (p)	Fat r (p)		Total r (p)	Node r (p)	Fat r (p)
Total talc by digestion	0.43 (0.05)								
Total birefringent particle counts	0.15 (0.51)	0.67 (0.001)							
Total birefringent particle counts, node	−0.07 (0.77)	0.59 (0.005)	0.81 (<.0001)						
Total birefringent particle counts, fat	0.53 (0.01)	−0.13 (0.58)	0.25 (0.26)	0.07 (0.76)					
Talc/cm^3 volume	0.57 (0.006)	0.87 (<.0001)	0.63 (0.002)	0.47 (0.03)	−0.06 (0.78)				
Birefringent particles per cm^3 total volume	0.33 (0.13)	0.42 (0.06)	0.82 (<.0001)	0.56 (0.008)	0.3 (0.19)	0.68 (0.0007)			
Birefringence per cm^3 node volume	0.07 (0.77)	0.51 (0.02)	0.90 (<.0001)	0.88 (<.0001)	0.18 (0.45)	0.64 (0.003)	0.87 (<.0001)		
Birefringence per cm^3 fat volume	0.51 (0.01)	−0.24 (0.30)	0.003 (0.99)	−0.1 (0.68)	0.61 (0.003)	0.16 (0.48)	0.45 (0.04)	0.13 (0.58)	
Age	0.28 (0.20)	0.26 (0.26)	0.35 (0.12)	0.32 (0.15)	0.16 (0.49)	0.22 (0.33)	0.26 (0.25)	0.36 (0.12)	−0.07 (0.75)

Node = lymph node tissue
Fat = fibroadipose tissue

adjusted for the level of surface contamination. Not unexpectedly, total counts always strongly correlated with counts per cm^3 of relevant tissues: e.g. total talc with total talc per cm^3 tissue volume (r = 0.87, p = 0.001); total birefringent particle counts in lymph node tissue with birefringent counts per cm^3 lymph node tissue (r = 0.88, p = 0.0001); and birefringent particle counts in fibroadipose tissue with birefringence counts per cm^3 fibroadipose volume (r = 0.61, p = 0.003). Talc counts per cm^3 tissue volume correlated with: birefringent particles per cm^3 tissue volume (r = 0.68, p = 0.007), and lymph node birefringent particles per cm^3 lymph node tissue (r = 0.64, p = 0.003), but not with fibroadipose birefringent particles per cm^3 fibroadipose tissue. Total birefringent particles per cm^3 tissue volume correlated best with lymph node birefringent particles per cm^3 lymph node tissue (r = 0.89, p = 0.001). Birefringent particle counts per cm^3 lymph node tissue were not correlated with fibroadipose birefringent particle counts per cm^3 fibroadipose volume. Age was not significantly correlated with any measure of nodal contamination.

Figure 2 and Table 3 illustrates the potential effect of surface contamination on the interpretation of the relationship between total talc (by digestion) per cm^3 tissue volume. Figure 2 illustrates that for any level of surface contamination, those who used talc in the genital area had a higher amount of talc than those who had not used talc genitally. Table 3 quantifies

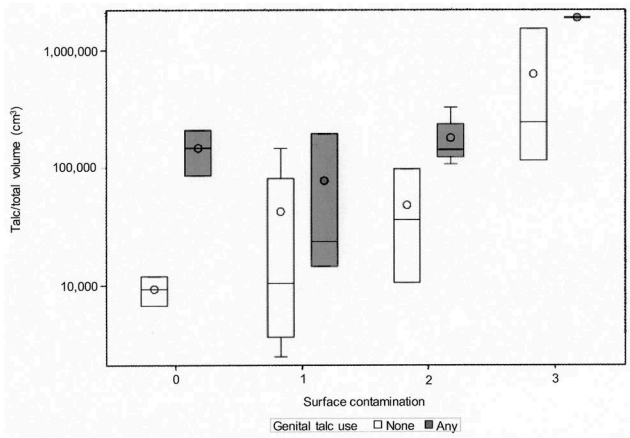

Figure 2. Talc/total volume for genital talc users and non-users by surface contamination This figure shows surface contamination scores (x axis) plotted against talc per tissue volume (y-axis, logarithmic scale), showing that for any level of surface contamination, those who used talc in the genital area had a higher amount of talc than those who had not used talc genitally.

Table 3. Geometric mean talc/total volume by genital talc use.

Talc/total volume	No genital talc use (n = 12) Geometric mean (95% CI)	Any genital talc use (n = 10) Geometric mean (95% CI)	p-value
Crude	35,049 (13,637, 90,079)	131,584 (46,787, 370,070)	0.08
Adjusted for surface contamination	29,926 (15,546, 57,605)	159,056 (77,491, 326,475)	0.004

this effect more precisely and indicates that, overall, the genital talc user had higher talc counts per volume of tissue than those who had not used talc, but the association was of borderline significance. After adjustment for level of surface contamination, the association became significant (p = 0.004) with the level of talc in nodal tissue at least five times higher in those who used talc genitally compared to those who had not.

Figure 3 shows correlative polarizing light microscopy, SEM, and EDX from case 18 in the digestate study (Table 1). Going clockwise from upper left, panel **A** shows polarized light microscopy (H&E, 200x), showing numerous birefringent particles (general size range 1 to 5 μm) within the macrophages of a left external iliac lymph node. This case was near the upper end of the range of particle abundances we observed. Panel **B** shows examples of two particles (labeled 1103 and 1104), identified by SEM on the digestate filter, each <5 μm diameter. Panel **C** shows the spectrum for particle 1103, with an Mg-Si atomic weight ratio of 0.6495, characteristic of talc. The other particle in **B**, 1104, had an Mg-Si ratio within 5% of the theoretical talc value (0.649).

In situ *SEM study*

Table 4 shows data for the second part of the study (19 lymph node specimens from 10 patients). The left-most two columns (case number and block letter) are

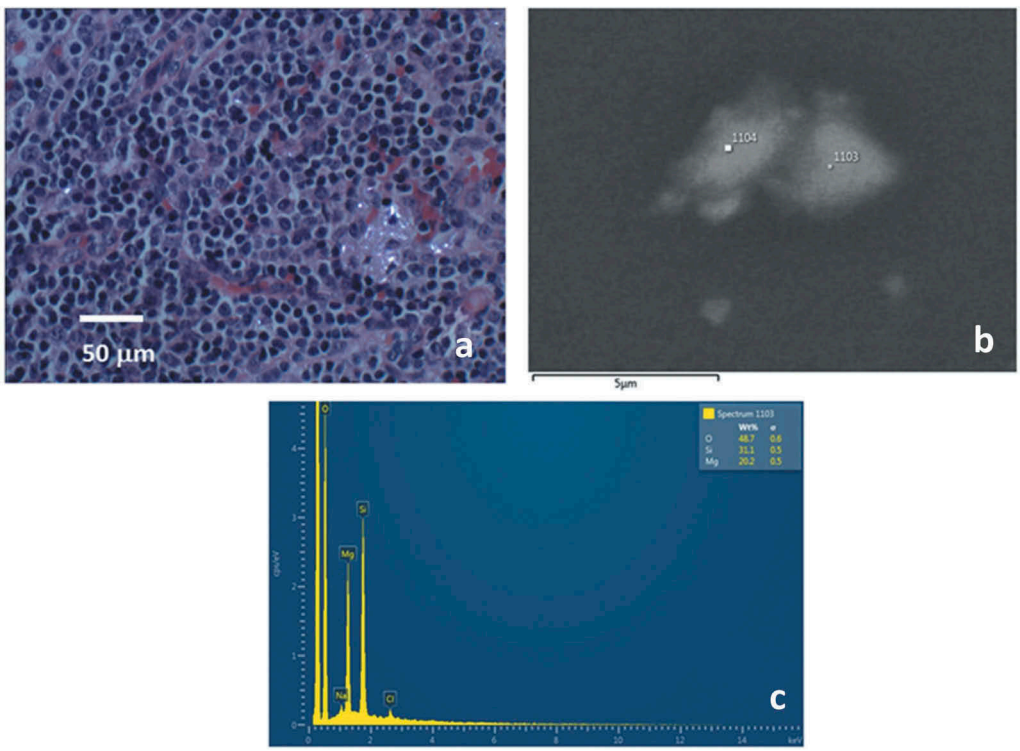

Figure 3. Correlative polarizing light microscopy, SEM, and EDX from case 18 in the digestate study (Table 1). Clockwise from upper left: **a**, Polarizing light microscopy, H&E, 200x, showing numerous birefringent particles (general size range 1 to 5 μm) within the macrophages of a left eternal iliac lymph node. **b**, Two particles (labeled 1103 and 1104), identified by SEM on the digestate filter, each <5 μm diameter. **c**, Spectrum for particle 1103, The Mg-Si atomic weight ratio is 0.6495, characteristic of talc. The other particle in **b**, 1104, had an Mg-Si atomic weight ratio within 5% of the theoretical talc value (0.649).

Table 4. Correlation between light microscopic birefringent particulates and in situ SEM analysis for talc particles.

Case number	Slide letter	Birefringent particles in lymph node tissue (total per slide)	Birefringent particles in surrounding fibroadipose tissue (total per slide)	Total birefringent particles in slide (columns C + D)	Number of talc particles in the block by in situ SEM
1	A	3	5	8	0
	B	55	7	62	5
2	A	5	2	7	9
3	A	2	0	2	0
	B	0	0	0	0
4	A	19	9	28	31
	B	3	1	4	5
5	A	>500	3	>500	65
6	A	6	4	10	0
	B	8	3	11	0
	C	16	4	20	0
7	A	7	3	10	1
	B	1	0	1	0
8	A	>100	3	>100	18
	B	>200	2	>200	43
	C	>100	5	>100	35
	D	>100	7	>100	24
9	A	8	6	14	1
10	A	15	>50	>50	12

In this part of the study, 19 pelvic lymph node slides on 10 ovarian carcinoma patients (with each patient having from one to four node specimens), showed the relationship of the numbers of birefringent particles (by light microscopy) within histological sections (separately categorized in lymph node and fibroadipose tissue components), and talc particles found by SEM/EDX at deeper levels in the tissue blocks corresponding to those sections (right-hand column). In case 9C, the vast majority of the birefringent particles were localized in only one of several lymph nodes visible in the slide. Note that cases with very numerous particle counts by light microscopy are designated simply as greater than a certain threshold.

fully de-identified and serve for identification purposes within the table only. The table shows the relationship of the numbers of birefringent particles by light microscopy within histological sections (separately categorized in lymph node and fibroadipose tissue components), and talc particles found by SEM/EDX on the block surface (following the preparation procedure) corresponding to those sections (right-most column). Consistent with our hypotheses, strong correlations using Spearman correlations were indeed evident between a) lymph node counts by light microscopy and the SEM total talc count ($r = 0.80$, $p < 0.0001$); and b) total particle counts by light microscopy and the SEM total talc count ($r = 0.79$, $p < 0.0001$). Fibroadipose tissue counts by light microscopy did not correlate with SEM total talc counts ($r = 0.32$, $p =$ not significant). In controlling for correlated observations from the same patient, Spearman correlations using one record per case were done for the six patients where more than one lymph node specimen was included in the study (among these patients, the specimen with the highest SEM talc count was the one selected). With this adjustment, strong correlations were still observed using Spearman correlations as evident between a) lymph node counts by light microscopy and the SEM total talc count ($r = 0.69$, $p < 0.03$); and b) total particle counts by light microscopy and the SEM total talc count ($r = 0.74$, $p < 0.01$), Fibroadipose tissue counts by light microscopy did not correlate with SEM total talc counts ($r = 0.16$, $p =$ not significant).

Figure 4 shows correlative polarizing light microscopy, *in situ* SEM, and EDX on case 9C from Table 4. Going clockwise from lower left, panel **A** shows numerous birefringent particles under polarized light microscopy (H&E, 400x) within the macrophages of a left external iliac lymph node. Panel **B** shows low-power backscattered electron imaging under SEM with several positive particles. Panel **C** shows an enlarged (cropped) view of the lower right-hand part of panel B. Three particles are labeled – 44, 45, and 46. Panel **D** shows the spectrum for particle 45, which showed an Mg-Si ratio of 0.643. Particle 44 was also within the 5% of the theoretical value of 0.649 and so was considered talc as well. Particle 46 had an Mg-Si ratio of 0.610, which falls just outside the 0.649 ± 5% range for talc, and so it was considered a nonspecific magnesium silicate.

A review of the non-talc particles found by *in situ* SEM in the 10 patients in Table 4 showed an aggregated total of 310, which based on their chemical composition would be regarded as likely birefringent. Of these, the most common were magnesium silicates outside the 5% theoretical range of the Mg-Si atomic weight spectral ratio for talc (113 total particles or 36%), aluminum silicates with or without magnesium (91 total particles or 29%), and calcium without phosphate (41, or 13%), with others accounting for the remaining 22%. Non-fibrous, non-talc silicates are known to have a longer dissolution time than talc in physiologic conditions; the dissolution time for talc is approximately 8 years for a 1 μm particle.[19] Thus, the component of non-talc silicates in pelvic tissues could proportionally rise over sufficient

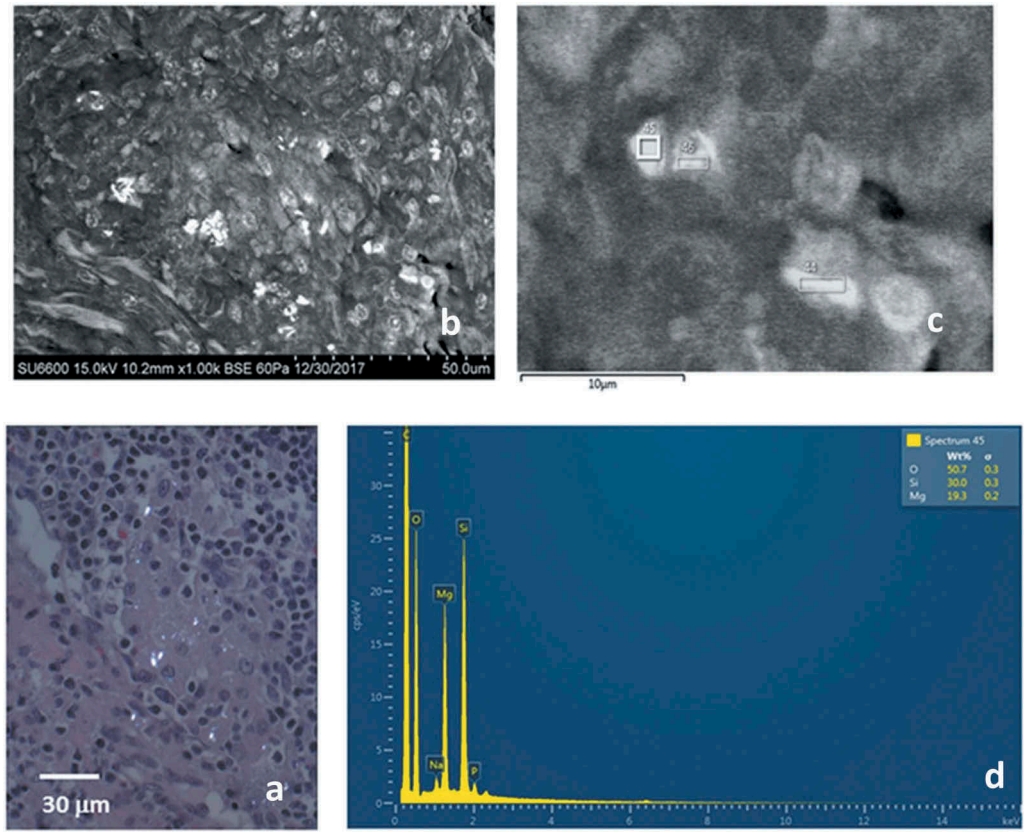

Figure 4. Correlative polarizing light microscopy, in situ SEM, and EDX on case 8C from Table 4. Clockwise from lower left: **a**, Numerous birefringent particles under polarized light microscopy (H&E, 400x) within the macrophages of a left external iliac lymph node. **b**, Low-power backscattered electron imaging under SEM with several positive particles. **c**, Enlarged (cropped) lower right-hand portion of **b**. Three particles are labeled – 44, 45, and 46. **d**, Spectrum for particle 45, which showed an Mg-Si atomic weight ratio of 0.643. Particle 44 was also within the 5% of the theoretical value of 0.649 and so can be considered talc as well. Particle 46 had an Mg-Si atomic weight ratio of 0.610, which falls just outside the 5% range for talc and so can be considered a nonspecific magnesium silicate.

elapsed time (years), even if the original exposure to talc was heavy.

To provide final evidence for our hypothesis that talc is an important part of specimen surface contamination, two authors (SM and JG) re-reviewed the 19 slides from the second part of the study (*in situ* SEM). The goal was to find cases in this group with surface contamination. We did not find any with a score of 3, but two cases (1B and 7A from Table 4) were chosen that, respectively, had contamination scores of 2 and 1 (with 100% agreement by pathologists SM and JG), and substantial amounts of evaluable surface area. On polarizing light microscopy, these cases showed a mixture of larger paper debris fragments and smaller (1–10 µm) birefringent particulates along the surface similar to those previously seen for many Table 1 cases., Respectively, for 1B and 7A, 13 and 5 small birefringent particulates were found by thorough examination of their surfaces in addition to larger paper debris. SEM of the tissue surface for block 1B (35 mm^2 analysis area) showed a total of 5 talc particles, and for 7A showed 1 talc particle (50 mm^2 analysis area). Given the 2.5 µm effective section thickness (electron beam analysis depth) and these relatively small surface areas, these SEM talc particle counts are significant, and are consistent with the light microscopic review. Thus, this portion of the study directly showed that surface contamination particles were talc, whereas previously, this had only been strongly implied by the results in Table 1. (See supplementary figure S1). In addition to the talc particles, 44 other exogenous particles were found across tissue surfaces of these two cases by SEM/EDX: 27 external mineral (mainly Si in combination with Mg and/or Al), 6 non-talc Mg-Si minerals, and 11 external metal.

Discussion

The accurate identification of talc in pelvic tissues is important because it documents exposure by demonstrating the presence of talc in these tissues and provides evidence in support of the role of talc in the epidemiological association with ovarian cancer in case-control studies.[9–13,15] The overall relative risk across the various positive studies is around 1.3, and where tumor histology data have been available for review, several common subtypes (serous carcinoma, endometrioid carcinoma, and serous borderline tumors) are most frequently involved in the association.[11,13]

Talc, when applied to the perineum, is believed to migrate to the upper genital tract, passing through the open tract to the fallopian tubes and eventually reaching the ovaries.[11,16] Talc may also gain access to the lymphatic system as a means of reaching pelvic organs and lymph nodes,[20,21], similar to the route to the pulmonary nodes of talc miners.[22] Lymph nodes of the pelvic region include several anatomic sub-classifications (inguinal, iliac, and paraaortic), with the common theme that they may receive lymphatic efferents from pelvic organs such as the ovaries and perineum and/or secondarily from other lymph nodes in the area. Ovarian carcinoma, especially serous, tends to metastasize early (when just one or two nodes are involved) to paraaortic nodes.[23] Full discussions of the lymphatic drainage/anatomy of the pelvic region are available in the literature.[20,21] Lymph nodes are often sampled during gynecologic surgery for tumor staging and assessment for metastatic disease. However, additional examination of these nodes for talc, especially in settings where genital exposure is known to have occurred, would add insight as to the ability of talc to migrate and lodge within pelvic tissues.

This study supports earlier observations that talc particles, from perineal exposure, can and do migrate to pelvic lymph nodes. Material with the microscopic and spectral features of talc was clearly demonstrated within the lymph node parenchyma in most of our cases, as scattered birefringent particles in the general size range 1–10 μm. Sometimes the material was visible within nodal macrophages, lending strong credence to a lymphatic migration route. Similar particles were also found in the fibroadipose tissue adjacent to lymph nodes, where they may have arrived via the lymphatic system, but more likely resulted from visibly present surface contamination pushed into the underlying fibroadipose tissue.

Our study took the additional critical step of comparing the light microscopic data to SEM digestion data, thereby going beyond the earlier study by Heller et al.[17] in scope, in addition to examining lymph nodes rather than ovaries. Like that earlier paper, we found high talc particle burdens in some digested samples. But because these correlated with contamination scores, we believe that the digestion counts are not fully reflective of clinically relevant talc exposure or its migration in the tissues. Instead, they are influenced by contamination, such as talc introduced by non-surgical gloves used for handling tissue and in the general lab environment during tissue collection and processing in the pathology laboratory. Thus, tissue digestion should not be regarded as a reliable quantification method for talc or contaminants of talc, especially where the collection and processing steps have not been rigidly controlled from the start. The correlation of contamination scores with counts of birefringent particles in fibroadipose tissue suggests that particles adherent to the surface (through contamination) may be pushed into the soft fibroadipose tissue, since it is typically the most peripheral type of tissue, with the nodal tissue usually deeper and encapsulated with a fibrous tissue capsule. The highly variable talc burdens found by digestive analysis and SEM, spanning approximately three orders of magnitude, are consistent with contamination influence, since the latter would be expected to vary considerably between procurement environments. However, this could also be observed in the range of burdens seen in a clinically exposed population with appropriate lab procedures/controls (Table 4).

Even though contamination played a role in total tissue counts, it was still the case that high talc burdens in the lymph nodes, when present, contributed to the SEM digestate results, hence producing the observed correlation between the two. Thus, it is likely that both contamination and clinically significant lymph node talc are reflected in the SEM digestate data. The main

problem in using digestion is that it likely raises the baseline for all patients and groups, thus potentially obscuring clinically significant differences, which would otherwise be observed if contamination were eliminated (as previously mentioned, Table 3 illustrates a robust demonstration of this effect).

By showing strong correlations between particle counts (polarized light microscopy) and *in situ* SEM analysis, the second part of our study demonstrated that the latter alternative is a better method of talc assessment than digestion, because the anatomic landmarks are preserved and surface contamination is not incorporated into the general talc count, as it is with tissue digestion. In combination with other parts of our study, this aspect also showed that the birefringent material in the lymph node tissue, is the clinically significant component related to talc exposure. Surface contamination can still be present, and our demonstration of talc on the surfaces of cases 1B and 7A by *in situ* SEM lent support to the conclusions from the first (digestion) part of the study.

A major strength of our study was the correlative light microscopic and SEM/EDX data for each case, with examination of anatomic locations in the former. This provided a key perspective in the evaluation of the talc burden data that a digestive study alone would not have given. In fact, this study demonstrates the broader principle that correlative histologic review is important in many areas of pathology – especially where digestion procedures are performed, and where the study of anatomic landmarks are needed to complement data from the latter. This is because the tissue is compartmentalized histologically, with different functions and significance for each component, a fact not always recognized by those who digest tissue routinely and use the resulting product completely in analyses such as Western blotting or mutational assays.[24]

Unfortunately, as part of our study, we were not able to also do *in situ* SEM/EDX on the intact tissues used for digestion in the first group of cases (22 patients). However, by showing that birefringent particles within lymph nodes were strongly correlated with the demonstration of talc inside the nodes by *in situ* SEM/EDX, the second part of our study filled that role, and thus 1) material in lymph nodes is likely reflective of the clinical exposure, 2) in this clinical setting and given our results, a substantial proportion of this birefringent material is likely to be talc, 3) surface contamination is common, and so with *in situ* SEM, it is important to discern the anatomic landmarks, and avoid analyzing surface particulates (as shown by our direct demonstration of talc on the surfaces of cases 1B and 7A in our auxiliary study to the cases in Table 4).

In addition to talc, much other commonly found birefringent material, such as that described in the Results section for the SEM analysis, is likely nonspecific particulate material which finds its way into the perineum through general living and hygiene practices. Another important point is that seeing particles by *in situ* microscopy, both light and SEM, requires a relatively large amount of material distributed within the tissues in order to find it. As a demonstration of this principle, Roggli and Pratt[25] showed that finding one asbestos body in a tissue section was indicative of at least 100 fibers per gram of tissue. The calculations we used to estimate particles/cm^3 of tissue volume (Table 1), starting with a count of birefringent particles in tissue sections, illustrate a similar principle.

In the long-studied and debated association between talc exposure and ovarian cancer, our study provides additional evidence that talc may enter pelvic tissues and ultimately be detected and measured in regional lymph nodes, and this relationship became especially strong when clinical use data was considered and surface contamination was corrected for statistically. This adds perspective to the known migratory capabilities and overall biological role/impact of talc. For some of the more heavily exposed cases in the second part of the study, we noticed that the large majority of birefringent material was localized in a single node, among several present on a given slide. This suggested that pelvic drainage/migration pathways for talc may be very specific, and focused on one or relatively few nodes as an endpoint – perhaps consistent with the concept of sentinel nodes in oncologic surgery.[26]

Our findings also suggest that in patients with ovarian cancer, clinicians may want to make broader inquiries into the past and present use

of talc by their patients. Similarly, pathologists may wish to pay greater attention to sampled regional lymph nodes. In addition to the usual study of these nodes for metastases, they may wish to examine macrophages more closely for exogenous particles including by polarized light. A positive finding may trigger clinical inquiries about exposure where it was not previously suspected. Our findings yield important insights as to the ability of talc to migrate to nodes, and under what conditions its identification in nodes and tissues is clinically meaningful and when not.

In conclusion, talc contamination of the surface of surgical pathology specimens is common. Exposure (such as perineal application), whether known clinically or not, often results in significant deposition of talc in the tissues. Correlative light microscopy is needed to assess the possibility of lab contamination, and to determine if talc is truly present in clinically meaningful locations in lymph nodes or other tissues.

Declaration of Interest Statement

The authors declare the following competing financial interest(s): JJG, DC and WW have served as consultants and provided expert testimony in talc and other environmental litigation. SM, YF, RS, MK, and LS report no conflicts of interest.

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Exhibit 78

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 1 - 2014

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RE: Docket Numbers 94P-0420 and FDA-2008-P-0309-0001/CP

Dear Dr. Epstein:

This letter is in response to your two Citizen Petitions dated November 17, 1994 and May 13, 2008, requesting that the Food and Drug Administration (FDA or the Agency) require a cancer warning on cosmetic talc products. Your 1994 Petition requests that all cosmetic talc bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." Additionally, your 2008 Petition requests that cosmetic talcum powder products bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer." Further, both of your Petitions specifically request, pursuant to 21 CFR 10.30(h)(2), a hearing for you to present scientific evidence in support of this petition.

We have carefully considered both of your Petitions. We are committed to the protection of the public health and share your interest in reducing the risk of ovarian cancer. Current regulations state that cosmetic products shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product. FDA may publish a proposal to establish a regulation prescribing a warning statement on behalf of a petitioner if the petition is supported by adequate scientific basis on reasonable grounds.

After careful review and consideration of the information submitted in your Petitions, the comments received in response to the Petitions, and review of additional scientific information, this letter is to advise you that FDA is denying your Petitions. FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.

For this reason and for the additional reasons described below, FDA is denying your Petitions.

I. Discussion

The basis of your request, throughout both Petitions, can be summarized as comprising three major points:

1. Talc may be associated with asbestos.
2. Talc is a carcinogen based on the findings of a 1993 National Toxicology Program study.
3. Epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As the points you raise in your Petitions concern the chemistry and toxicology of talc, the epidemiology associated with talc use, and the etiology of ovarian cancer, commensurate reviews were conducted to assess your request.

Chemistry Findings:

Asbestos is a known carcinogen and your first major point is that talc may be associated with asbestos. As evidence that talc cosmetic products contain asbestos, you first cite a 1968 survey of 22 talcum products that found fiber content averaging 19% in all 22 products. This author further concludes that "the fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits …"

You then cite a follow up study from 1971-1975 that examined 21 samples of consumer talcums and powder and concluded that cosmetic grade talc was not used exclusively in these products. This study found the presence of asbestiform anthophyllite and tremolite, chrysotile, and quartz. From these two citations, one may infer that currently available talc-containing cosmetic products are presently contaminated with asbestos, a known carcinogen. Unfortunately, you did not present any original data on the chemical composition of talc currently being used in cosmetics talc products or data linking these findings to currently used talc.

It has been reported in the scientific literature that most talc products in world trade are impure as a result of the geological processes involved in the formation of talc deposits. Further, talc containing asbestos fibers such as tremolite asbestos or chrysotile are sometimes encountered. However, large deposits of high purity, asbestos-free talc do exist and talc purification techniques have been developed which can be used to improve talc quality. Thus, while it has been reported in the past that cosmetic talc has been contaminated with asbestos, it has been also reported that asbestos-free talc deposits do exist. In addition, techniques do exist for the purification of talc in order to improve its quality. You have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed, since the data submitted is almost 40 years old.

Because safety questions about the possible presence of asbestos in talc are raised periodically, in 2009 FDA conducted an exploratory survey of currently marketed cosmetic-grade raw material talc and finished cosmetic products containing talc. This survey analyzed cosmetic-grade raw material talc from four suppliers out of a possible group of nine suppliers we had requested talc samples from, along with thirty-four talc-containing cosmetic products currently available in the Washington, D.C. metropolitan area for the presence of asbestos. In order to cover as broad a product range as possible, samples identified for testing included low, medium, and high priced products, along with some from "niche" markets. The cosmetic products identified as containing talc included eye shadow, blush, foundation, face powder, and body powder.

The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. While FDA found this data informative, the results were limited by the fact that only four suppliers submitted samples and by the number of products tested. They do not prove that all talc-containing cosmetic products currently marketed in the United States are free of asbestos contamination. As always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health. You may wish to see more on this survey on our website at http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm.

Toxicology Findings:

Your second major point is that talc is a carcinogen with or without the presence of asbestos-like fibers. The basis to this claim is that in 1993, the National Toxicology Program (NTP) published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.

This NTP report concluded that cosmetic-grade talc caused tumors in animals, even though no asbestos-like fibers were found. The report made the following observations:

- There was some evidence of carcinogenic activity in non-asbestiform talc from inhalation studies in male rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland.
- There was clear evidence of carcinogenic activity of talc in female rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.
- There was no evidence of carcinogenic activity of talc in male or female mice exposed to 6 or 18 mg/cubic meter.

However, this study lacks convincing scientific support because of serious flaws in its design and conduct, including:

- The investigators used micronized talc instead of consumer-grade talc resulting in the experimental protocol not being reflective of human exposure conditions in terms of particle size.

- Investigators conceded that they had problems with the aerosol generation system; whereby, the target aerosol concentrations were either excessive or not maintained during 26 of the 113-122 weeks of the study.
- The study did not include positive and negative dust controls which would have permitted an "exact assessment" of the talc's carcinogenicity relative to the two control dusts.

In light of these shortcomings, a panel of experts at the 1994 ISRTP/FDA workshop declared that the 1993 NTP study has no relevance to human risk.

In addition, we reviewed relevant toxicity literature (consisting of 15 articles from 1980 to 2008), not cited in your Petitions, to determine if there was additional support at this point in time to for your suggested warning label. Scientific literature on studies of acute exposure effects, subchronic exposure effects, chronic exposure or carcinogenicity effects, developmental or reproductive toxicity, and genotoxicity effects were reviewed. As a result of the review of this relevant literature, FDA did not find enough additional support at this point in time for your suggested warning label.

Epidemiology and Etiology Findings:

Your third major point is that epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

After consideration of the scientific literature submitted in support of both Citizen Petitions, FDA found:

1 The exposure to talc is not well-characterized; it is not known if the talc referred to in the scientific studies was free of asbestos contamination; various consumer brands or lots of talc were not identified; and contamination of talc by asbestiform minerals or other structurally similar compounds was not ruled out.

2 Several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled confounding that result in spurious positive associations between talc use and ovarian cancer risk.

3 Results of case-controls studies do not demonstrate a consistent positive association across studies; some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0 and dose-response evidence is lacking.

4 A cogent biological mechanism by which talc might lead to ovarian cancer is lacking; exposure to talc does not account for all cases of ovarian cancer; and

5 there was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure.

6 The conclusion of the International Agency for Research on Cancer that epidemiological studies provide limited evidence for the carcinogenicity of perineal use of talc based body powder and the IARC classification of body-powder talc as group-2B, a possible carcinogen to human beings, is persuasive, but the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer.

Per the etiology review, approximately 10% of epithelial ovarian cancers are associated with inherited mutations. The remaining 90% of epithelial ovarian cancers are not related to these genetic mutations are non-hereditary. They have been historically classified based on histology as borderline/low malignant potential, serous, endometrioid, mucinous, and clear-cell.

Two theories have historically dominated on the cause of epithelial ovarian cancer and these are the "incessant ovulation hypothesis" and the "gonadotropin hypothesis." In addition to these endogenous factors, the role of exogenous factors via retrograde transport of noxious substances (e.g. carcinogens, particulates such as talc and asbestos, endometriosis and infectious agents) from the vagina and uterus into the Fallopian Tubes and peritoneal cavity have been studied extensively as a possible risk factor for ovarian cancer.

While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers. However, there has been no conclusive evidence to support causality.

The best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking.

Request for hearing

In addition to your request for a warning label, you also requested a hearing, under 21 CFR 10.30(h)(2), so that you can present scientific evidence in support of your petitions.

Under this regulation, FDA may deny a citizen petition request for a hearing if the data and information submitted (even if accurate), are insufficient to justify the determination urged. In consideration of your request, we conducted an expanded literature search dating from the filing of the petition in 2008 through January 2014. The results of this search failed to identify any new compelling literature data or new scientific evidence.

Since we find that the data and information are insufficient to justify the determination you request and we did not identify any new compelling literature data or new scientific evidence, FDA is also denying your hearing request.

II. Conclusion

FDA appreciates the goals of the Cancer Prevention Coalition and FDA supports the goal of reducing the rate of ovarian cancer. Although FDA is denying the Cancer Prevention Coalition's petitions for the reasons discussed above, the Agency shares your commitment to the public health.

Sincerely,

Steven M. Musser, Ph.D.
Deputy Director for Scientific Operations
Center for Food Safety
and Applied Nutrition

Drafted: J. Gasper, OCAC, 2/28/14
Comments: L. Katz, OCAC, 3/3/14
Revised: J. Gasper, OCAC, 3/4/14
Cleared: N.Sadrieh, OCAC, 3/4/14
Cleared: LMKatz, OCAC, 3/5/14
Reviewed: FHogue, OCAC: 3/614
Cleared by:Musser:3/13/14
F/T:SRussell, OCAC 3/18/14

Exhibit 79

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

----------x

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

MDL NO: 16-2738 (FLW)(LHG)

----------x

THIS DOCUMENT RELATES TO ALL CASES

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VIDEOTAPED DEPOSITION UNDER ORAL EXAMINATION OF

SONAL SINGH, M.D., M.P.H.

January 16, 2019, 9:07 a.m.

- - -

REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR

- - -

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Deposition of SONAL SINGH, M.D., M.P.H., held at the Beechwood Hotel, 363 Plantation Street, Worcester, Massachusetts, pursuant to Agreement before Janet Sambataro, a Registered Merit Reporter, Certified Realtime Reporter, Certified LiveNote Reporter, and a Notary Public within and for the Commonwealth of Massachusetts, on January 16, 2019, commencing at 9:07 a.m.

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P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services. Today's date is January 16, 2019, and the time is 9:07 a.m.

This video deposition is being held in Worcester, Massachusetts, in the matter of Talcum Powder Litigation, MDL No. 2738, for the United States District Court, District of New Jersey.

The deponent today is Sonal Singh, M.D., M.P.H.

Counsel will be noted on the stenographic record.

The court reporter is Janet Sambataro and will now swear in the witness.

SONAL SINGH, M.D., M.P.H., having been duly sworn, after presenting identification in the form of a driver's license, deposes and says as follows:

DIRECT EXAMINATION

BY MR. ZELLERS:

Q. State your name, please.

A. Sonal Singh.

Q. Dr. Singh, we are here to take your deposition as an expert for the plaintiffs in the Talc MDL; is that correct?

A. Yes.

Q. You are familiar with depositions?

A. Yes.

Q. You've given a number of depositions in your career?

A. I don't know about a number. Yes, I have.

Q. Can you estimate for us the number of depositions that you've given?

A. I think I've provided that list in the last five years.

Q. I understand. My question is a little different.

How many have you given in your career?

A. I can't tell you in my career. Maybe ten. Approximately.

Q. Have you ever testified at trial?

A. No.

Q. You understand today that I'm going to ask you a number of questions and other counsel may as well; correct?

A. Yes.

Q. Please don't answer any question that you don't understand.

Can you do that?

A. Yes.

Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you.

Can you do that?

A. Yes.

Q. If you answer a question that I ask, then I'm going to assume that you understood it. Is that fair?

A. Yes.

Q. You are here today pursuant to a Notice of Deposition, which we have marked as Exhibit 1.

(Notice of Oral and Videotaped Deposition of Sonal Singh and Duces Tecum marked Exhibit 1.)

BY MR. ZELLERS:

Q. Is that correct?

A. Yes.

MR. ZELLERS: Katherine, when I mark an exhibit, I'm going to need to hand them to you.

MS. MCBETH: Sure.

MR. ZELLERS: Thank you.

BY MR. ZELLERS:
Q. Did you have an opportunity to review Deposition Exhibit 1 before today's deposition?
A. Yes.
Q. Have you brought with you or provided to counsel for production all materials in your possession that are responsive to the Notice of Deposition?
A. I have.
MR. ZELLERS: I will mark, as Deposition Exhibit 2, your report in this matter dated November 16 of 2018.
(Rule 26 Expert Report of Sonal Singh, MD, MPH marked Exhibit 2.)
BY MR. ZELLERS:
Q. Is that correct?
A. It is. It doesn't have the references.
Q. Deposition Exhibit 2 is just a copy of your report itself. It ends at Page 66.
Attached to your report were some additional materials; is that right?
A. Yeah. Yeah. I just want to make sure because when I refer to the report, I understand it to include references and tables and so on.
Q. Your report includes everything that

was produced by plaintiffs' counsel as part of that report; is that right?
And, Dr. Singh, I'm going to mark separately a number of the attachments --
A. Okay.
Q. -- to your report. Right now, I'm just trying to identify, is the body of your report --
A. Yeah.
Q. -- what we have identified and marked as Exhibit 2?
MS. PARFITT: And if I may, Mr. Zellers, object. The body of the report, Dr. Singh may include as the body of the report plus all of its attachments.
So just so the record is clear, but I understand how you'd like to conduct it, and that's fine.
MR. ZELLERS: Understood.
BY MR. ZELLERS:
Q. Your counsel today has provided us with two bankers boxes of your report, plus all of the references from the report. Is that correct?
A. Yes.
Q. You also have brought that along with you; is that right?

A. Yes.
Q. If at any time today you need to look at any of those documents, they're available, and you're free to do that. Understood?
A. It is understood.
Q. You had attached or provided with your report a curriculum vitae, which I understand has been updated; is that right?
A. Yes.
MR. ZELLERS: We will mark your updated CV or curriculum vitae as Deposition Exhibit 3.
(Sonal Singh, MD, MPH, FACP, curriculum vitae marked Exhibit 3.)
MR. ZELLERS: Folks, I believe that Ms. Parfitt has distributed to you, before the deposition, Exhibit 3.
BY MR. ZELLERS:
Q. Can you tell us, just briefly, in what respect has Exhibit 3 been updated from the CV that was produced with your report in this matter?
A. A few publications, and then I was elected to the fellowship of the American College of Physicians on January 1st. So I'm an FACP, and, yes, just a couple of publications,

presentations.
Q. Is the curriculum vitae that we have marked as Deposition Exhibit 3 complete and up to date?
A. Yes. Up to January 3rd. Yes.
Q. Of 2019?
A. 2019. Yeah.
Q. Are there any further additions or corrections that need to be made to that CV?
A. No.
MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And that goes from Page 67 to Page 75.
Q. Is that correct?
A. Yes.
(List of references marked Exhibit 4.)
MR. ZELLERS: Deposition Exhibit 5 is also from your report, and it's a listing of additional materials and data considered.
(Additional Materials and Data Considered marked Exhibit 5.)
BY MR. ZELLERS:
Q. Is that right?
A. Yes.

MR. ZELLERS: Deposition Exhibit 6 is an updated list of materials that defendants were provided on January 13th of 2019.

(Updated Materials List marked Exhibit 6.)

BY MR. ZELLERS:

Q. Is that correct?

A. Yes.

MR. ZELLERS: Folks, I need one more of those back. Can I get one more? Thank you.

Deposition Exhibit 7 is a listing of the trial testimony and expert deposition testimony that you have provided in the last five years.

(List of Trial Testimony marked Exhibit 7.)

BY MR. ZELLERS:

Q. Is that right?

A. Yes. Actually, I have provided them an update, as well, of that. So I don't know if that was with you, but --

Q. You have brought with you today an updated list of expert deposition testimony for the last five years?

A. Yes. No. 7 is the update.

MR. ZELLERS: We will mark the updated trial testimony list as Deposition Exhibit 8.

(List of Expert Deposition marked Exhibit 8.)

MR. ZELLERS: And I understand that's out of order, but I premarked one other exhibit.

BY MR. ZELLERS:

Q. What is the difference between Deposition Exhibit 8, your updated list of deposition testimony, and Exhibit 6, which is the list of testimony you provided with your report in November?

A. Yes. So there's an updated deposition in a medical-legal case regarding standard of care.

Q. You've added that --

A. Yes.

Q. -- to --

A. No. 7.

Q. -- what we have marked as Deposition Exhibit 8?

A. Yes, it is.

Q. In addition to the materials that we have marked already, which were provided, other than the updated CV and the updated expert

testimony list, several additional documents that counsel for plaintiffs has indicated are responsive to the deposition notice.

Let me mark these. I have not had a chance to look at them yet substantively.

THE WITNESS: Sure.

MR. ZELLERS: But I will and may, at a later time today, have some questions for you.

THE WITNESS: Actually, I will say there's a substantive document that's not here. That's the table of rating that I created for the report, and that should be part of the report.

MR. ZELLERS: Let me see if I can find that.

BY MR. ZELLERS:

Q. It would be helpful to have that marked as well; is that right?

A. Yes.

MR. ZELLERS: I will mark, as Deposition Exhibit 9, the Amstar rating of reviews, Pages 77 and 78 from your full report.

(Table 1 AMSTAR marked Exhibit 9.)

BY MR. ZELLERS:

Q. Is that right?

A. Thank you.

MR. TISI: That was No. 9?

MR. ZELLERS: No. 9.

Let's go off the stenographic record. You can keep the video going.

(Discussion off the stenographic record.)

MR. ZELLERS: Let's go back on the stenographic record here.

Doctor, counsel for plaintiffs have requested, and I am agreeable to marking a complete copy of your report, including all of the reference list and other materials that we've marked individually, so the complete copy of your report with all attachments, we will mark as Deposition Exhibit 10.

(Rule 26 Expert Report of Sonal Singh, MD, MPH, with attachments marked Exhibit 10.)

BY MR. ZELLERS:

Q. Have we, though, marked individually your complete record -- strike that.

Have we marked individually your complete report prior to marking Exhibit 10?

A. Yes.

(Letter dated June 1, 2015

marked Exhibit 11.)
BY MR. ZELLERS:
Q. The documents that were produced by counsel this morning, Deposition Exhibit 11, is a June 1st, 2015 letter with Janssen Pharmaceuticals at the top to you from a Dr. Zanca. Is that right?
A. Yes.
Q. Is this inviting you to a program?
A. Yes. Consultation for a panel on products discussion manufactured by Johnson and Janssen Pharmaceuticals.
Q. You're producing this in response to the request asking for all communications between yourself and any Johnson & Johnson company; is that right?
A. That's what I understood it to be, but -- yeah.
Q. You've gone and you've made a search, and in the search for additional records responsive to the Notice of Deposition, which we marked as Exhibit 1, you have brought these additional documents that we're marking here; is that correct?
A. Well, I wouldn't say I made a search.

I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this interaction with Johnson & Johnson employees.
Q. Are you comfortable that you have brought with you today all of the documents that are responsive to the Notice of Deposition?
A. Yes.
(Email string with top e-mail dated December 27, 2018 marked Exhibit 12.)
MR. ZELLERS: All right.
BY MR. ZELLERS:
Q. Deposition Exhibit 12 is an e-mail string. The very last e-mail is from you to -- well, it's to Michelle Parfitt. I'm assuming that you were forwarding to Ms. Parfitt just the e-mail below, which is from you to Mr. Restaino and then, apparently, the substantive e-mail is at the bottom of the first page of Exhibit 12.
And this is a communication e-mail from you to Lee-May Chen and others; is that right?
A. Yes.
Q. The subject is "Up-to-date references." And the section on epidemiology and risk factors of ovarian cancer; is that right?

A. Yes.
MS. PARFITT: And for the record, Mr. Zellers, and we can go ahead and redact the copy later, but just so the record is clear, that communication at the top to me from Dr. Singh was simply, we asked him, do you have any communications, and then he sent it to me.
MR. TISI: We'll redact the part with your agreement.
MR. ZELLERS: Yes. We can do that at a break --
MS. PARFITT: At a break.
MR. ZELLERS: -- or, you know, at the conclusion --
MS. PARFITT: I appreciate that. Thank you.
MR. ZELLERS: -- of the deposition.
BY MR. ZELLERS:
Q. Do you -- strike that.
The date of your e-mail at the bottom of Page 1 is December 13th of 2018; is that right?
A. Yes.
Q. You had been retained as an expert?
A. Yes.
Q. And had submitted, in fact, your expert

report that we have marked previously; is that right?
A. Yes.
Q. In this communication, Exhibit 12, do you at all identify yourself as a paid, retained expert for the plaintiffs in the talc litigation?
A. No. This was just a communication about references, and I did not.
MR. ZELLERS: Dr. Singh, the next set of documents that you have brought with you and that we will mark collectively as Exhibit 13 are your invoices.
(Invoices from Dr. Singh marked Exhibit 13.)
BY MR. ZELLERS:
Q. The first invoice is dated July 14 of 2010. There's a total of five invoices.
The last invoice is from July 11, 2018, to November 19, 2018. Is that right?
A. It should be 2017, not 2010. I'm sorry. You mentioned 2010.
Q. And the date is 2017?
A. Yeah. I wanted to correct that.
Q. No. Thank you for correcting that.
I also have not had a chance to review,

substantively, the invoices.
A. Sure.
Q. And I don't think we have a complete copy. I'm going to ask you some questions in a bit.
A. We do have a complete copy. I mean, in terms of --
Q. No. I understand that Exhibit 13 is a complete copy of your invoices.
A. Yeah.
Q. That you now have the copy in front of you. I don't have the copy in front of me. Keep it. I'll have some questions for you a bit later.
Have we now marked all documents that are responsive to the Notice of Deposition which you have produced here today? And let me withdraw that.
Have we now marked all of the documents that you have produced in response to the Notice of Deposition?
A. Yeah. And I think that, you know, there were some updated materials that I reviewed that are part of this list.
Q. All right. And we need to be more

specific --
A. Sure.
Q. -- as you understand from doing this before.
You are referring to the list of updated materials that was produced about a week ago?
A. Yeah.
Q. And that is Deposition Exhibit -- well, strike that.
Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?
A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.
Q. Anything else that you have responsive to the deposition notice that we have not marked?
A. Give me a second. Let me read.
MS. PARFITT: If we can go off the stenographic record for one moment while he's doing it.
MR. ZELLERS: Sure.
(Discussion off the stenographic record.)

(Plaintiffs' Steering Committee's Response and Objections to the Notice of Oral and Videotaped Deposition of Sonal Singh and Duces Tecum marked Exhibit 14.)
MR. ZELLERS: Back on the stenographic record.
Dr. Singh, at the request of plaintiffs' counsel, we will mark and incorporate, as an Exhibit 14, the objections that plaintiffs have filed to the deposition notice.
MS. PARFITT: Thank you.
BY MR. ZELLERS:
Q. Have we identified and marked all of the documents that you have produced pursuant to the Notice of Deposition?
A. We have.
Q. To your knowledge, there are no additional documents that you have in your possession to produce; is that right?
A. I don't have any additional documents.
Q. The report that we have marked as Deposition Exhibit 10, does that contain all of the opinions that you intend to offer at trial?

A. Actually, it's Deposition Exhibit 2.
Q. I understand.
A. Sorry. I'm a little confused here.
Q. That's fine. We don't want you to be confused. And I asked you in the beginning to tell me if you were getting confused.
We have marked Deposition Exhibit 10, which contains all of the attachments --
A. Okay.
Q. -- that we have separately marked; is that right?
A. Yeah. Yeah.
Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?
A. Yes.
Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions that you intend to offer at any trial or hearing in this matter?
A. Well, I mean, it's hard to say it contains all the opinions because there have been some updates since then and, you know, science evolves.
Q. Go ahead. Finish your answer.

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A. Science evolves, and, you know, we update our opinions. So it's not like you offer an updated opinion one day and that stays that way.
Q. Dr. Singh, this is our opportunity to ask you questions about the opinions that you have formed in this matter.
As of today, does your report, which we've marked as Exhibit 2 and also --
MS. PARFITT: 10.
Q. -- Exhibit 10, does that include all of the opinions that you intend to testify to at any trial or hearing of this matter?
A. Yes. In terms of the causation opinions, it does. But in terms of what additional evidence has been reviewed or what additional evidence has come up that, you know, supports or refutes that, that might have changed.
Q. Dr. Singh, do you have any new or additional opinions today that you intend to offer at any trial or hearing of this matter beyond the opinions that are included in your report which we've marked as Exhibit 2 and Exhibit 10?

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A. I'm sorry. I'm just not -- it's not like I don't want to answer. I'm trying to understand. When you say "additional opinions," does it just mean like a causal opinion or does it mean --
Q. Dr. Singh, you have done this before; right?
A. Yeah. I'm trying to understand and I'm trying to be responsive.
Q. This is the defense opportunity to ask you what opinions you intend to offer at any hearing or trial of this matter.
As of today, do you have any additional opinions beyond the opinions that are set forth in your report which you intend to offer at any trial or hearing of this matter?
A. I don't -- yeah -- I mean, it's, you know, the opinions that I've offered are included in the report.
Q. Does your report identify -- and by "report," we can refer to the report that we've marked as Exhibit 10.
A. Mm-hmm.
Q. Does that report identify everything that you are relying on in forming the opinions

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that you intend to provide at any hearing or trial in this matter?
A. No. I'm relying on additional evidence since then that has become available on this.
Q. Let's -- I will ask you a new question.
Are all of the materials that you are relying on in forming the opinions that you expect to testify to at any hearing or trial, identified either in your report, which we have marked as Exhibit 10, or the updated list of materials, which we have marked as Exhibit 6?
A. Yes.
MS. PARFITT: And 5.
THE WITNESS: Okay. That's the part of the whole report.
MR. ZELLERS: Yes.
BY MR. ZELLERS:
Q. Exhibit 5 had previously been produced as part of your report; is that right?
A. Yes.
Q. Is your report accurate?
A. Yes.
Q. Is your report complete?
A. Yes, it is. It has some typos, but...
Q. As we go along, if there's a typo --

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strike that.
Are there any typos that are substantive typos?
A. No. But sometimes it's we and they. I can point that out at some point in time.
Q. Are there any documents that were in your possession that you produced to counsel responsive to the deposition notice that have not been produced here?
A. No. Not that I can think of.
Q. When were you first contacted by anyone regarding the talc ovarian cancer litigation?
A. So this was in 2017 by Attorney John Restaino and Attorney Parfitt. I don't know the exact day, but it has to be the, you know, spring or summer of 2017. Spring or summer.
Q. Your invoice, your first invoice is dated July of 2017; is that right?
A. Yeah. But, you know, it just covers a period of background. It's not that they contacted me and may have contacted me prior to that.
Q. Sometime in the first part of 2017, you were contacted by Mr. Restaino and by Ms. Parfitt; is that right?

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A. Yes.
Q. Anyone else?
A. No.
Q. What attorneys have you met with or communicated with in the talc ovarian cancer litigation other than Ms. Parfitt and Mr. Restaino?
A. So Attorney Chris Tisi, and then I have communicated on the phone with Attorney Gates. Is that -- no. Margaret?
Q. Margaret Thompson?
A. Thompson. Yeah.
Q. Do you know Margaret Thompson?
A. I mean, I know her as an attorney. I just spoke to her on the phone for 30 minutes.
Q. Have you ever met in person with Ms. Thompson?
A. No.
Q. Have you ever had any communications or interactions with Ms. Thompson other than the 30-minute-or-so phone call?
A. No.
Q. When was that conversation with Ms. Thompson?
A. I don't know. A couple of days ago.

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Yeah.
Q. It was in preparation for the deposition; is that right?
A. Yes.
Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?
A. With the lawyers, I've spent -- yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise.
Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?
A. No. Not that I can recall.
Q. Do you understand that you are -- or strike that -- have been retained as an expert by plaintiffs in the MDL talc ovarian cancer litigation?
A. Right now, I do. Yes.
Q. Is there any other ovarian cancer litigation matter that you have been retained in?
A. No.
Q. When you were retained back in early 2017 by Mr. Restaino and Ms. Parfitt, what were

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you asked to do?
A. So to clarify, I don't know I was retained at that time.
I was asked to consult on and provide, you know, a review and look at -- look at the literature on this topic. So I'm not sure -- depending on semantics, you can define it as being retained or, you know -- I don't think we had an "agreement," but I was asked to provide a consultation on that matter. And these invoices include that consult.
Q. In the first part of 2017, what were you asked by counsel for plaintiffs in the talc litigation, ovarian cancer talc litigation, to do?
MS. PARFITT: Objection. Limit your response to communications with regard to simply the requests, not the conversations.
A. Yeah. So I was asked to review, you know, the literature on talcum powder products and ovarian cancer.
Q. Had you ever done that before?
MS. PARFITT: Objection. Form.
A. I mean, when I say "review," yes, I had read about talcum powder products and ovarian

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cancer.
Q. You were asked to make a systematic review of the literature relating to talcum powder products and ovarian cancer; is that right?
A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other -- from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.
Q. At some point, you were retained, agreed --
A. Yes.
Q. -- to work with the attorneys for plaintiffs; is that right?
A. Yes.
MS. PARFITT: Objection. Form.
Q. Were you ever given any new or additional assignment in the MDL talc ovarian cancer litigation other than to do a literature review?
MS. PARFITT: Objection. Form.
A. Well, I mean, I guess I was, you know,

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asking the causal question that is the use of talcum powder products a cause of ovarian cancer.
Q. You looked at the literature --
A. Mm-hmm.
Q. -- to try to determine if you could answer that question; is that right?
A. Yeah. So we looked at -- I looked at the literature and, you know, obviously, looked at other documents and performed a methodology, and we can discuss that in detail later.
But the primary question of interest is -- was, is the use of perineal use of talcum powder products associated with and causally related to the development of ovarian cancer.
Q. That has been the request from plaintiffs' counsel to you in terms of providing expert opinions in this matter; is that right?
A. Yes.
Q. When were you first asked to prepare a report setting forth your opinions?
A. Again, I can't recall the specific timelines. I'm sorry. It's been a while.
Q. Were you asked by plaintiffs to assume any facts?
A. No. I mean, at that time, you know,

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and even prior to that, I was reading the literature. I was, you know, agnostic to it.
And, yeah, I didn't -- in fact, I didn't form an opinion on this topic until -- until the very end of, you know, 2018.
Q. When you say you were "agnostic" --
A. Mm-hmm.
Q. -- to this issue, whether or not talcum powder products are associated with ovarian cancer, do you mean that you had not formally come up with or developed any opinions prior to becoming involved as an expert for plaintiffs?
MS. PARFITT: Objection. Form.
A. Yeah. So my -- what I mean is I had not systematically reviewed the literature to form an opinion whether talcum powder products is, so I had not done the processes required to, you know, develop an opinion.
Q. All right. You have now done that and you're here to talk about it; is that right?
A. Yes.
Q. Plaintiffs' counsel have paid you for your time to review documents, the literature, prepare a report, and render your opinions; is

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that right?
A. Yes.
Q. How much are you charging per hour for your time in this case?
A. $600 an hour.
Q. You have invoices in front of you.
What is the total value of the time that you've spent on the talc ovarian cancer litigation, whether that's been billed or not billed, paid or not paid?
A. I can't calculate the time. I can calculate --
Q. Can you estimate it for us?
A. I don't want to give a number that's inaccurate; right? I mean, these are accurate numbers. But I will just have to sum it up --
Q. Let's try to do this as quickly as we can.
A. Yeah.
Q. The five invoices that you've marked or -- strike that -- that we have marked as Deposition Exhibit 13 --
A. Mm-hmm.
Q. -- does that capture all of your time on the ovarian cancer talc litigation through

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November of last year?
A. Yes.
Q. Is there any additional time that you have spent on the talcum powder litigation up through November of last year that's not reflected in the invoices we've marked as Exhibit 13?
A. No.
Q. All right. First invoice, what is the total?
A. 9,300.
Q. The second invoice, total?
A. Twenty, one, zero, zero.
Q. 21,000?
A. 20,100.
Q. Next invoice, total?
A. 5,100.
Q. Next invoice, total?
A. 19,200.
Q. Last invoice, total?
A. 40,800.
Q. Since November of 2018, can you estimate for us the number of hours that you have spent on this matter?
A. So, I mean, apart from three to five

hours that I spent with the lawyers, I don't know. Maybe I've spent 10, 15 hours on my own. Maybe more. I just don't have that exact number. I'll have to look.

Q. At some point, you will submit an invoice --

A. Yes.

Q. -- for your time; is that right?

A. After today. Yeah.

Q. Have you been disclosed as an expert in any other talcum powder proceeding aside from this case?

A. No.

Q. What percent of your professional time do you currently spend performing work as a consultant?

A. Yeah. It could be -- you know, varies. It could be 20 to 30 percent of my time. Sometimes 20 percent.

Q. Has that 20 to 30 percent of your professional time spent working as a consultant, has that been consistent for the past five, ten years?

A. Yeah. So, actually, it's been less in the past, sometimes a little more, but, you know,

overall, I would average out, you know, sort of as I was preparing over the last five years, it would probably be 15 to 20 percent, but, you know --

Q. Currently, though, best estimate is 20 to 30 percent; is that right?

A. Over the last six months. Yes.

Q. What percent of your income is from consulting on litigation matters?

A. Again, I can't give you my gross income. I mean, I --

Q. I don't want your gross income. I'm asking just for -- I just want to know a percentage of your income that comes from consulting in litigation cases.

A. Well, again, you know, consulting is not just litigation for me. As I said, I've consulted, you know, including for J&J, Eli Lilly, others, that's, you know, on my CV. Overall, and other, you know, insurers. So it's not just -- first of all, it's not litigation consulting that I do.

Q. Dr. Singh --

A. Yes.

Q. -- listen to my question, if you can.

A. Okay.

Q. What percentage of income is from consulting on litigation matters? Give us an estimate.

A. Okay. Yeah. Maybe 30 percent. I'm doing my best to give you --

Q. Is that your -- you're here to be truthful; correct?

A. Yeah.

Q. Is 30 percent of your income from consulting on litigation matters, is that your best estimate as you sit here today?

MS. PARFITT: Objection. Some clarity as to over what period of time?

A. Yeah. Over five years, I mean, that's my best estimate.

Q. Is it a little bit more now?

MS. PARFITT: Objection.

A. Well, over the last year, yes, but over five.

Q. Over the last year, what are you working on? You're working on the talc litigation; is that right?

MS. PARFITT: Objection. Form.

Q. Doctor, did you hear my question?

A. Yeah. Yeah.

Q. What other litigations are you serving as an expert for?

A. Viagra.

Q. You're an expert for plaintiffs in Viagra; is that right?

A. Yes.

Q. What other litigations are you serving as an expert for plaintiffs in?

A. None other than that, that I know of.

Q. Are you still working as an expert for plaintiffs in the Lipitor litigation?

A. That ended several years ago, as far as I recall.

Q. You list two Tasigna cases against Novartis.

Are you still working on those cases?

A. That ended in, I think, in -- yeah, it ended.

Q. You list on your expert testimony, 2018; is that right?

A. Yes. I mean, but I listed everything that was -- I have done in the five years. It doesn't mean that those are ongoing.

Q. You are no longer serving as an expert,

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to your knowledge, in the Tasigna cases; is that right?
A. Yes.
Q. How about the Rahmoeller versus Walmart litigation, is that still ongoing?
A. That stopped, but, you know, it's been a year since I've heard anything, so I don't know.
Q. You also provided testimony in a matter of Brufett versus Washington University.
Is that still ongoing?
A. That has ended.
Q. Is it fair to say that all of the cases in which you have been retained in the past --
A. Sure.
Q. -- as an expert for plaintiffs involving a pharmaceutical company defendant have involved prescription medications?
A. Yeah. Prescription medications, issues of systems. I mean, that's my area of research.
Q. How much of your work is for plaintiffs versus defense as a litigation consultant?
MS. PARFITT: Objection. Form.
A. Yeah. I mean, over the last ten years, I've provided opinions to both sides, but I have

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not been, you know -- when you say how much of your work, is it time spent or --
Q. In terms of time spent, most of your work is for plaintiffs; is that right?
A. I would say, yeah, 70 percent. Yeah.
Q. And it can be more than 70 percent; is that right?
MS. PARFITT: Objection to form. Objection to form.
A. Well, it depends, again, for frame of time and, you know, if you say yes, in the last year, yes. More than --
Q. Last year, it's been more than 70 percent --
A. Sure.
Q. -- for plaintiffs; is that right?
A. Yes.
Q. Have you ever been retained in a case involving asbestos?
A. No.
Q. Have you ever been involved in a case -- strike that.
Have you ever been retained in a case involving personal injuries?
MS. PARFITT: Objection. Form.

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A. I don't understand. Like, what is a personal injury? Is it like somebody -- MVA kind of case or --
Q. Well, you've been involved in Lipitor. You have been involved in a number of other litigations. Let me withdraw that question. Let me make it a little more precise.
Have you ever been retained in a case involving cosmetic products?
A. No.
Q. In the preparation of your report, did you review the other expert reports provided by plaintiffs in this MDL litigation?
A. I mean, other than those cited, I have not had a chance to review them.
Q. The updated materials list that you have produced here today, which we've marked as Exhibit 6, it contains a number of expert reports from plaintiff experts in the MDL talcum powder ovarian cancer litigation; is that right?
A. Yes.
Q. What is Exhibit 6? It says "Updated materials."
Does that mean updated materials that you have reviewed and considered?

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A. They were provided to me at some point in time between November 15th, and I haven't even -- I have actually not reviewed any of the expert reports other than those that have been cited in my report.
Q. This list of updated materials is something that was provided to you by plaintiffs' counsel; is that right?
A. Yes.
Q. Have you reviewed any of the materials that are on the updated materials list, which we have marked as Exhibit 6?
A. Yeah. I had a chance to review some of them.
Q. Which materials that are identified on Exhibit 6, updated materials, have you actually looked at, reviewed, and considered?
A. Yeah. So, I mean, I was already aware of the Health Canada assessment and, you know, so that's -- I've reviewed.
I have reviewed, obviously, the Up to Date, that childs sent.
I have reviewed the state of the science. I have reviewed --
Q. What do you mean "state of science"?

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Where is that listed?
A. No. 2. No. 2.
Q. All right. You've reviewed Chen Up to Date. You have reviewed the second reference, Committee on the State of Science.
A. Yeah.
Q. Have you reviewed the Evolving Paradigms and Research and Care?
A. Yes.
Q. The Draft Screening Assessment, Talc Health Canada?
A. Yes.
Q. The EFSA Science Committee?
A. Yes.
Q. The EPA documents that are listed?
A. No.
Q. The FDA Ingredients Talc?
A. No.
Q. The Fadak Burnola citation?
A. Yes.
Q. The Federal Register, Volume 81?
A. Yes.
Q. Have you reviewed the Kemp hearing opinion and order?
A. I don't think so.

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Q. The Keys Model Information Bias?
A. Yes.
Q. Kunz?
A. Yes.
Q. Official Journal of the European Union?
A. No.
Q. Qiao, Q-I-A-O?
A. No.
Q. Risk Management Scope, Talc Health Canada?
A. No.
Q. You have not reviewed any of the plaintiff expert reports submitted in this matter. Is that your testimony?
A. Yeah. They were provided to me and, you know, I formed my opinion independent of them.
Q. Have you reviewed any of the reports prepared and submitted by plaintiffs that are identified in your updated materials?
A. No. Except if any of them were cited, that's the one that I reviewed it in.
Q. Yup. Did you review Talc Canada Plain Language Summary?
A. Yes.

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Q. Did you review Talc Information Sheet, Health Canada?
A. Yes.
Q. Talc Potential Risk of Lung Effects?
A. Yes.
Q. Task Force on Science Risk Assessment?
A. Yes.
Q. The Weed Reference?
A. Yes.
Q. And the Zervomanolakis citation?
A. Yes.
Q. Have we covered all of the materials that you've reviewed on the updated materials list? Is that right?
A. Yes.
Q. Have you communicated or had any discussions with any of the other plaintiffs' experts in the talc ovarian cancer litigation?
A. No.
Q. Have you reviewed any deposition or trial transcripts from prior talcum powder cases?
A. Not prior cases, but I reviewed the deposition of Dr. Plunkett.
Q. Plunkett?
A. Plunkett.

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Q. Have you reviewed any other depositions of experts that have been taken in the MDL ovarian cancer talcum powder litigation?
A. No.
Q. Did you conduct any independent investigation to reach your opinions?
A. I mean, I -- my opinion is independent of these.
Q. As I understand it, what you did is you were asked by plaintiffs to review and consider and form an opinion regarding the causal question. Is that right?
A. Yes.
Q. To do that, you went and you reviewed a number of different literature sources; is that right?
MS. PARFITT: Objection. Misstates his opinion. He indicated he had reviewed some prior to that.
MR. ZELLERS: Ms. Parfitt, just object, form. And let's not have speaking objections.
MS. PARFITT: And you won't find that I will. I want to make sure we have an accurate record.
I can wait until the very end and do a

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recross, but I'm trying to clean it up.
BY MR. ZELLERS:
Q. Doctor, go ahead.
A. I didn't get the question. Can you repeat?
Q. Sure. The question is: You were asked to form an opinion by plaintiffs. You went out and you reviewed the literature.
You considered the literature and you formulated an opinion; is that right?
A. Yes.
MS. PARFITT: Objection.
A. And it was an independent opinion.
Q. An independent opinion based upon your review of the literature; is that right?
A. Yeah. Based upon my review of the literature and the documents and, you know, whatever was available to me.
Q. And those -- all of those materials that you reviewed, considered and relied upon have been included in the exhibits that we've marked in this deposition; is that right?
A. That is correct.
Q. Was there anything that you asked plaintiffs' counsel for to prepare your report

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that you were not provided with?
A. No.
Q. Did anyone assist you in the preparation of your report?
A. Well, I may have asked them to print, like, these things and, you know, I may have asked my -- I had means to print some articles when I was preparing that.
Q. Do you have a staff?
A. Yes.
Q. All right. Who is your staff?
A. I have several staff. I have, you know, three offices.
Q. So you have three offices?
A. Yes.
Q. In those three offices, do you have folks who help you?
A. Yeah.
MS. PARFITT: Objection to form.
Q. Do you have folks who do research?
MS. PARFITT: Objection. Form.
A. So, I mean -- so I have a dual appointment in my research, and so I have clinical staff and my research staff. I have people who work with me on projects. They are

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not necessarily the ones who may have helped me in printing articles.
Q. My question is: Who helped prepare your report other than yourself?
MS. PARFITT: Objection. Objection. I believe you've asked that. He's answered it.
A. Okay. Let me answer.
Q. Sure. Go ahead, Doctor. Please answer.
A. I prepared my report.
Q. I understand you prepared your report.
My question is: Did anyone assist you in preparing your report?
MS. PARFITT: Objection.
A. No.
Q. You were provided some materials by plaintiffs' counsel; is that right?
A. Yes.
Q. You reviewed some of those materials, but not all of those materials; is that right?
A. Yes.
Q. In terms of the references, Exhibit 4. And that is identified as Pages 67 through 75 in your full report that we marked as Exhibit 10.
But looking at your references, Exhibit 4,

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some of these references were provided by counsel for plaintiffs to you; is that right?
MS. PARFITT: Objection.
A. Yes.
Q. Some, you went out and found on your own; is that right?
A. Well, it's not that way. It's the majority of the references, I would say 95 percent of, are my own work, and, you know, I had questions about the product and the mechanism, what additional documents were available.
And that's a process. And documents were provided, and they need to be cited and are cited.
Q. Are you able to tell us, of the references that you cite, Deposition Exhibit 4, which ones came from plaintiffs' counsel and which ones you came up with on your own?
MS. PARFITT: Objection. Form.
A. Sure.
Q. You could do that if we went through one by one?
A. Yeah.
Q. Let me ask you the same question with

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respect to the additional materials and data considered, Exhibit 5.
Do you see that?
A. Yes.
Q. What's the difference between Exhibit 4, references, and Exhibit 5, additional materials and data considered?
A. So as I went about and did my, you know, systematic review and, you know, umbrella review, I gathered all the materials and, you know, I included studies and data that provided original data on the causal question that we discussed.
Q. Doctor, my question was simply, what's the difference between references and additional materials and data considered?
A. So the additional materials are those that were, I would say, you know, reviewed, were still reviewed in forming the opinion, but they are not -- they don't -- they don't form the basis of my opinion.
Q. The materials that you relied on in forming your opinion are what you've set forth as your references, Exhibit 4; is that right?
MS. PARFITT: Objection.

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A. Yeah. I mean, and then things that, you know -- obviously, for the report, it is the references. Yeah.
I did rely on these to review them and, you know --
Q. Did you -- strike that.
MS. PARFITT: For the record, that was Exhibit 5.
MR. ZELLERS: Well, no -- well, the references is Exhibit 4. The additional materials and data considered is Exhibit 5.
MS. PARFITT: Correct.
BY MR. ZELLERS:
Q. So looking at Exhibit 5, additional materials and data considered, were some of these materials provided to you by counsel for plaintiffs?
A. Yeah. They may have been. These are data considered. So I'm not as familiar with these as --
Q. Have you -- are you finished?
A. Yeah. I'm not -- I mean, I reviewed them. I, you know --
Q. Is it your testimony that you have reviewed and considered each and every one of the

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additional materials and data considered, items that are listed in Exhibit 5?
A. By reviewed and considered, I mean, have I read every word of it? No. I reviewed and considered.
Q. Who prepared the additional materials and data considered list?
MS. PARFITT: Objection.
A. I prepared the list, but I asked them also to help me with what materials they had sent.
Q. The lawyers for plaintiffs; is that right?
A. Yes.
Q. So in your documents, you do have a listing of the materials that were provided to you by plaintiffs' counsel for consideration; is that right?
MR. LOCKE: Objection. Misstates the testimony.
A. I'm sorry. Can you repeat?
Q. Sure. The question is: You do have, because you requested it, a listing of the documents and materials that were provided to you by plaintiffs' counsel for you to consider;

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correct?
MS. PARFITT: Objection. Misstates his testimony.
He didn't say he got a list.
MR. ZELLERS: Okay. Ms. Parfitt, please, form, foundation. You know, he can testify, and whatever he's testified to, it's part of the record.
MS. PARFITT: Sure. And, Mr. Zellers, I am not trying to interrupt your deposition, trust me on that, but I do want some clarity to the record.
MR. ZELLERS: Great. That's what we're doing right here.
MS. PARFITT: Well --
MR. ZELLERS: We've now asked the question two or three times.
BY MR. ZELLERS:
Q. Do you have the question?
MS. PARFITT: It's a little different. But go ahead.
A. So I had asked for additional materials in understanding the causal question between talcum powder products and ovarian cancer.
Q. What additional materials did you

request?
A. I requested additional materials regarding what are the constituents of talcum powder products. I -- you know, additional materials regarding testing of talcum powder products -- I -- you know, anything to, you know, enhance my understanding whether there's evidence to support or refute what we are seeing in the epidemiologic studies about an increased risk of ovarian cancer with talcum powder products.
Q. When you requested these materials, testing materials, ingredient materials and any other materials, did you want to see all of the materials that were available so that you could form your opinion?
MS. PARFITT: Objection. Form.
A. All is -- you know, there's only so many hours. I mean, you know, I think I wanted to see as much as, you know, was relevant to forming an opinion.
Q. Well, you asked for records of testing and you were provided with records, and we'll take a look at it --
A. Sure.
Q. -- that purport to show that there is

asbestos or asbestos has been found in talcum powder; correct?
A. I mean, that's not the only -- that's not only --
Q. Understood.
MS. PARFITT: Excuse me. Let him finish his answer, if you will, please. I'm not sure he was done. Appreciate that.
Q. Are you done?
A. No. I'm not. I want to finish my answer.
Q. Okay.
A. So I requested documents because I wanted to understand what constitutes talcum powder products, and whether it is asbestos or whether it is other heavy metals, that's sort of a separate answer, and we can discuss that, and I'm sure we will.
But I wanted to understand the constitution of the product and, you know, whether there were additional studies on, you know, whether it was mechanisms that -- so because -- so that's what the request was for.
And the documents were provided. And my review, looking at the complexity and volume of

material, I can tell you, there's not enough time to review all of it. I mean, if somebody has, that's great. I can't.
Q. Are you done?
A. Yes.
Q. Did you, when you made that request, intend for plaintiffs to provide you with all of the information that was available related to testing or related to ingredients or whatever other issues you requested documents on?
MS. PARFITT: Objection. Form.
A. Yes.
Q. All right. In your report, you cite -- and this is in references -- to the depositions of witnesses in the talcum powder litigation. For example, and let's take a look at Exhibit 4, your references, Cite No. 4 is to the deposition of Linda Loretz.
Did you review this?
A. Yes, I did.
Q. And who is she?
A. I don't recall offhand, who she is.
Q. Is that information that was provided to you by plaintiffs' counsel?
A. Yes.

Q. Who is Joshua Muscat, reference list, Cite No. 5?
A. I think he did one of the meta-analyses. He's an author of one of the meta-analyses as well.
Q. Who is Alice Blount, Cite 27?
A. Yeah. They did a study on talc and also I was deposed on that.
Q. Did you request that deposition or was that provided to you?
MS. PARFITT: Objection.
A. I requested information on -- as I said, my request wasn't for deposition -- you know, all documents that helped me answer the causal question.
Q. Whether they support plaintiffs' position or refute plaintiffs' position; is that right?
A. To answer the causal question. That's what --
Q. You wanted, though, all relevant documents, whether they supported plaintiffs' position or whether they refuted plaintiffs' position; correct?
A. To answer the causal questions. I

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don't --
Q. Can you not answer that question?
MS. PARFITT: Objection. I believe --
A. I'm answering your question.
MS. PARFITT: -- he did.
Q. My question is: When you requested documents from plaintiffs' counsel on various topics, did you expect to receive whatever documents may support plaintiffs' position and whatever documents may refute plaintiffs' position?
A. Yes.
Q. All right. Who is John Hopkins, reference item -- strike that -- reference list, Cite 33?
A. I think it's -- yeah. It's a deposition on behalf of J&J, I think.
Q. Do you know who Mr. Hopkins is?
A. No, I don't.
Q. Do you know what role he had with talcum powder?
MS. PARFITT: Objection. Form.
A. I mean, he was deposed in this litigation and he provided testimony.
Q. The question is: Do you know what role

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Mr. Hopkins played in and with talcum powder?
A. He was providing testimony on behalf of the company. Is that --
Q. Other than that, do you know anything about what he did on behalf of the company?
A. No.
Q. Do you know what his positions were?
A. I don't recall.
Q. Do you know what his duties and responsibilities were?
A. I don't review that as a part of my deposition, is to review positions and do responsibilities.
Q. And who is Julie Pier, Item 35?
A. She was testifying on behalf of Imerys, I think.
Q. Do you know her position?
A. I don't review -- you know, she was testifying for the company, as that's as far as I know. Again, I don't know what role she was playing and what she does.
Q. Did you read, for each of these depositions that you reference and cite to, did you read just that section or did you read the entire transcript?

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A. So we can -- we can go back to the sections where I cite these and then we can discuss. Is that okay?
Q. No. Well, and if you need to -- if you can't answer a question, tell me you can't answer a question.
My question is: For these five or six folks who you have quoted a snippet from their deposition, did you review their entire transcript or did you just review an excerpt?
MS. PARFITT: Objection to the form.
A. So the answer will be, we have to go one by one.
Q. All right. For Mr. Hopkins, did you review his entire deposition?
A. No.
Q. For Ms. Pier, did you review her entire deposition?
A. No.
Q. For Ms. Blount, did you review her entire deposition?
A. I recall, yes.
Q. Yes, you did?
A. Yes.
Q. For Ms. Loretz, did you review her

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entire deposition?
A. Yes.
Q. Did -- strike that.
For Mr. Muscat, did you review his entire deposition?
A. Yes, I did.
Q. Did you review all of the exhibits to those depositions?
A. Again, those are pages and pages of documents. I don't know that -- if I reviewed every single page of it.
Q. Is it your practice, outside of litigation, to rely on excerpts of deposition testimony?
A. Well, I mean, when you say "excerpts of depositions," when I reviewed evidence, when I try to gather evidence, as I said, you know, I was trying to answer the causal question; I try to gather all relevant evidence to the relevant causal question at hand.
And sometimes these are unpublished documents, and sometimes these are regulatory documents and sometimes, as is in this case, they are depositions. And this approach is quite consistent with other -- other approaches, such

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as those conducted by, you know, Health Canada.
I mean, they clearly state that, you know, you gather all relevant available evidence.
Q. That was your goal; is that right?
A. Yes.
Q. Did Health Canada review deposition testimony of company witnesses, to your knowledge?
A. Well, they were not available to them.
Q. When you practice, outside of being a litigation consultant, do you rely on excerpts of deposition testimony?
A. Well, again, you know, outside of this, when I do papers -- I mean, I do include unpublished or whatever you can collect, whether -- whether it's excerpts of -- I mean, I haven't -- if I look at my past papers, I can't say that I've used excerpts of deposition transcripts.
Q. Did -- strike that.
You also cite company documents in your list of references; is that right?
A. Which one is that?
Q. Exhibit 4.
A. Which company?

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Q. Well, for example, Item 116 refers to an Imerys document, item 63 refers to a document or set of documents produced by the Johnson & Johnson defendants; correct?
A. What was the second one? I'm sorry. You said 116 and then?
Q. Yes. Sixty --
MS. PARFITT: 63.
Q. 63.
A. I'll have to go back and see what do they cite about, to refresh my memory.
Q. As you sit here, you don't remember what those documents are, do you?
A. Yeah. Yeah. I'd have to go back.
Q. Is that correct?
A. Yeah. I mean, I have to go back to my report and see them.
Q. My question is: Did plaintiffs' counsel provide you with a large set of J&J and Imerys company documents and you went through and whittled them down, or did they provide you with select documents?
MS. PARFITT: Objection. Form.
A. Well, I mean, I feel it's a large set. As you can see, I've reviewed, you know, as much

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as humanly possible.
Q. My question is a little more specific. I'm talking now just about any documents produced by Johnson & Johnson defendants or any documents produced by Imerys defendants.
You do cite to several of those in your reference list; correct?
A. Yes.
Q. You were provided those documents by counsel for plaintiffs; correct?
A. Yes.
Q. Were you provided a large set of materials, company documents from the J&J defendants and from the Imerys defendants, or were you provided with select documents?
MS. PARFITT: Objection. Form.
A. I mean, these are company documents. I mean, what is the difference between the two? Like explain to me by example.
Q. Were you provided a box of J&J documents or documents produced by J&J for your review by plaintiffs' counsel?
MS. PARFITT: Objection. Form.
A. I don't know. I mean, they provided documents. I see them as documents. I don't see

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a difference between. You can -- you know, you can make that connection.
Q. Let me do it this way.
A. Sure.
Q. Are the documents that you reviewed relating to those produced by J&J or produced by Imerys, do you list those in your references, Exhibit 4, and your additional materials and data considered, Exhibit 5?
A. They are listed. Yes.
Q. All right. When you are doing your day job, outside of your litigation consulting work, do you rely on internal company documents?
MS. PARFITT: Objection. Form.
A. I mean, I have relied on company documents. When you say "internal company documents," that's, you know -- yeah. I have relied on company documents. We have relied on company trial registries for publications. We have relied on -- whether you're talking about company communication, that's different.
But in terms of if we have data available from the company, there's no reason not to rely on that.
Q. I'm talking about company

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communications, the types of documents that you cite from or produced by J&J and by Imerys in your reference list.

Those are not the types of materials that you typically would rely on if you were doing a study for publication; correct?

MS. PARFITT: Objection. Form.

A. And, again, I've just said that, you know, I gathered all the relevant evidence, as would -- you know, as a methodology that's acceptable and considered.

But, you know, in my previous reviews, I've not had access to -- access to those documents. And that's the only -- that's the only place where you can get access to these documents.

Q. The answer to my question is no, you know, when you publish articles, you do not rely on internal company documents or communications as you are in this litigation matter; correct?

MS. PARFITT: Objection. Form.

A. The reason is because there's a confidentiality order. And so you can't say you can't publish articles when you can't access them. I mean, there's a chicken and egg, here, right?

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Q. Understood.

The answer, though, to my question is yes; correct?

MS. PARFITT: Objection. Form.

A. The reason is because these documents --

Q. Doctor, you need to answer the question.

MS. PARFITT: Wait, Mr. Zellers. Excuse me. Let the witness answer the question.

MR. ZELLERS: I'm asking him to answer the question and then I'll be happy to move on.

MS. PARFITT: No. You're telling him, say yes. He's trying to answer your question.

Ask him again. He'll answer the question. He's done it twice.

Q. Do you need me to repeat the question?

A. Yes, please.

MR. ZELLERS: Could you read the question?

I'll ask it again.

Q. Dr. Singh, when you publish articles, you do not rely on internal company documents; correct?

MS. PARFITT: Objection. Misstates his

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testimony.

A. I've already stated that when I publish articles, the approach is to gather all relevant, available evidence.

And I have, in fact -- you can go back at my articles -- and included data from company documents in various systematic reviews and meta-analyses. So this idea that I have not relied on company documents is -- you know, is not.

The question is about deposition transcripts and communiques. Those are generally not available in the published domain, and even for this particular instance, you know, for there's a confidentiality order. I'm just trying to explain what happens.

Q. So that our record is clear, when you talk about internal communiques, we're talking about internal communications, in this case, materials that you have been provided by plaintiffs that have been produced by J&J and by Imerys.

Those are not the types of documents that you typically have available and rely upon in your published work; correct?

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MS. PARFITT: Objection. Misstates his testimony.

Q. Is that correct, Doctor?

MS. PARFITT: Objection. Misstates his testimony.

A. These are just not available to form an opinion in the published domain.

Q. You have an additional --

THE WITNESS: Can I take a break?

MR. ZELLERS: Sure. Of course. At any time.

THE WITNESS: Sorry about that.

MR. ZELLERS: No. That's fine.

THE VIDEOGRAPHER: Off the record. 10:22 a.m.

(A recess was taken.)

THE VIDEOGRAPHER: Here begins media No. 2 in today's deposition of Sonal Singh, M.D., M.P.H. Back on the record, 10:35 a.m.

BY MR. ZELLERS:

Q. Dr. Singh, are you ready to continue?

A. Yes, I am.

Q. When we broke, we were looking at the additional materials and data considered list, which we have marked as Deposition Exhibit 5.

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Do you have that?
A. Yes.
Q. There are some documents on this list that have a preface of Imerys. And if you look on Page 87, you list those documents out. And then turning to Page 88, there's a series of documents that begin with J&J.
Do you see those?
A. Yes.
Q. Did you rely on those documents in informing your opinions?
A. No. I mean, I reviewed -- I don't know if I reviewed them in full. I just -- you know, they were provided to me.
Q. That is, the set of documents that were provided to you by counsel for plaintiffs; is that right?
A. Yes.
Q. Are you able, as we sit here, to tell me what those documents are?
A. Yeah. I mean, for example, some of them is, you know, duplicative of expert reports that are listed here. I don't know by number and number, J&J, what that means.
Q. I'm referring to, for this series of

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questions, just to the other materials that you have listed, the ones that begin with Imerys. So starting at Item 2 on Page 87. And then also including the documents that begin J&J that go through Item 23 on Page 88.
Are you able to identify and tell us what those documents are?
A. I mean, I was provided them. I don't know what specifically they are, you know.
Q. Do you know how they were compiled?
A. No. I'm not aware of the process.
Q. Do you know what percentage of internal documents, internal to Johnson & Johnson companies and to Imerys, have been produced in the case that appear on your reliance list?
A. I'm not aware of that proportion.
Q. Did you request any additional J&J or Imerys documents other than the ones that were provided to you by plaintiffs' counsel?
A. So, it's hard to say request additional. I requested question -- materials to answer my question. How would I know what additional -- you know, I requested materials.
Q. The way it worked is you asked plaintiffs for materials that would be helpful to

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answer the causal question in this case; is that right?
A. Yes.
MS. PARFITT: Objection.
Q. You did not have access to internal documents of J&J companies or of Imerys; is that right?
A. Yes.
Q. You asked for those documents, the ones that would be relevant to you in forming an answer to the question you were asked of plaintiffs' counsel; correct?
A. Yeah. Relevant to consider or support or refute. Yeah.
Q. The documents that were provided to you are the documents that appear with a J&J preface -- preface and an Imerys preface in the reference list, Exhibit 4, and in the additional materials and data considered list, Exhibit 5; correct?
A. Yes.
Q. Once you got those documents and you looked at those documents -- and you're not sure you looked at all of them; is that right?
A. Yes. I did not. I mean --

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Q. All right.
A. -- because it is not possible to look at all of them.
Q. Did you make any follow-up request for additional company documents, either documents produced by J&J or documents produced by Imerys, of plaintiffs' counsel?
A. I was inundated with these, and I don't think it was practical of me to request for additional documents.
Q. In terms of internal company documents and communications produced either by Johnson & Johnson and by Imerys, the only documents you reviewed are the ones that were hand selected by lawyers for plaintiffs; is that right?
MS. PARFITT: Objection. Form.
A. The documents that I reviewed are listed, you know, in 4 and 5.
Q. My question --
A. I don't know what -- so you're asking me to infer what they hand selected; right? I mean, whether they provided all, whether they provided hand selected, that's not my -- I don't know that. You know that. But I don't.

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So how can I answer that they were hand selected?
Q. The company documents that you reviewed, internal company documents, they came from plaintiffs; is that correct?
A. Yes.
Q. The updated materials list, we marked that as Exhibit 6.
Those are materials that were provided to you by plaintiffs' counsel; is that right?
A. No. I submitted -- I mean, I had access to several of these documents, you know, after the submission of my report, and I reviewed them and I actually sent them some of them. So...
Q. What documents on this list did you provide to plaintiffs and what documents on this list -- we're looking at Exhibit 6 -- did they provide to you?
A. Like I had the Fadak article. I had the Health Canada Assessment. They provided the submitted reports. I had the Weed article. They provided the Zervo -- I don't know how to pronounce that name. Yeah.
So, yeah, I had access to some of these, and

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I provided the up-to-date article, and the remainder, they provided.
MR. KLATT: May I interject? I didn't understand the very first article you said. It sounded like dark.
THE WITNESS: Fadak.
MS. PARFITT: F-A-D-A-K.
THE WITNESS: Fadak, that's a paper --
MR. KLATT: Okay. I see. Thank you.
THE WITNESS: That's a 2015 paper.
MR. KLATT: I saw it. Thank you.
BY MR. ZELLERS:
Q. When did you review the materials that are listed on the updated materials list, Exhibit 6?
A. So, again, maybe we circle back earlier when I said I did not review all of them, like I did not review the expert reports. Yeah.
Q. Of the materials that you did review, on the updated materials list, when did you review those?
A. Sometime between December and January.
Q. It was after you had prepared your written report and produced it; is that right?
A. Yes.

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Q. It's fair to say you did not rely on the updated materials list in forming your opinions and preparing your report in this case; correct?
A. Yeah. I did not rely on this, on these materials in preparing the report, but several of these materials are, you know, are helpful in explaining my opinions on this, which were, you know, provided in the report.
Q. Have you published anywhere your theory that baby powder causes ovarian cancer?
A. I don't consider it my theory. I mean, several other people have studied this. I don't know how many studies. There have been more than 30 studies.
So I don't consider it my theory. But, no, I have not published a study on it.
Q. Do you plan to publish on this?
A. Yes, I do.
Q. Are those plans underway?
A. Well, I mean, a lot of it will, again, depend on, you know, the questions you asked about how much of this material will become eventually -- you know, I have signed a confidentiality order. So, you know, how much is

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allowed to be published.
And so, you know, a lot of it will depend on, I guess, the permission of the judge, who allows -- who oversees these kind of -- I would like to, eventually.
Q. Have you previously published on any topic relating to talc and ovarian cancer?
A. No.
Q. Have you conducted any test or experiments to confirm your theory that talc migrates to the ovaries and causes cancer via inflammation?
A. So, again, that is not a theory that I have propounded, that talc migrates through the ovary, that talc migrates up to cause ovarian cancer, that I have evaluated the epidemiologic studies, which show a causal link between talc and ovarian cancer, and several other investigators, some of them which I cite, have provided evidence that -- of talc-induced, you know, migration.
So it's not my theory, as you say.
MR. ZELLERS: Move to strike as nonresponsive. Try to listen.
Q. My question is, I think, a simple

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question.
Have you, Dr. Singh, conducted any test or experiments to confirm your statement in your report that talc migrates to the ovaries and causes cancer via inflammation?
A. No. I have not done any experiments.
Q. Can you identify for me a single article that identifies inflammation anywhere in a woman's reproductive tract resulting from external genital talc application?
MS. PARFITT: Objection. Form.
A. Can you repeat the question?
Q. Sure. Can you identify for me a single article that identifies inflammation anywhere in a woman's reproductive tract resulting from external genital talc application?
A. I mean, again, this is, you know, when I reviewed -- so this relates to the biological question about talc. And when I reviewed the biological evidence, I was on migration and inflammation, I was looking for evidence, support or refute that.
And there's studies that show that talc migrates through HS, you know, whatever, hysterosalpingography, and induces inflammation.

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I mean, the definitive study is not there.
And, again, I did not do these studies. So I can only rely on people who have done such studies.
Q. Can you cite a single study, animal or human, that traces externally applied talc up through the reproductive tract to the ovaries?
MS. PARFITT: Objection. Form.
A. Again, but I do not believe that's necessary to, you know, provide my causal opinion in support of a causal hypothesis.
MR. KLATT: Objection. Nonresponsive.
Q. Is the answer to my question, no?
MS. PARFITT: Objection. Form.
A. No, with context.
Q. Health Canada Risk Assessment, that was not something that you included in your references or materials considered as part of your report; is that right?
A. Yes. It was not available at that time.
Q. All right. It is listed, the Health Canada Risk Assessment is listed in your updated materials list that we got over the weekend; correct?

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A. Yeah. It was available to everyone in December.
Q. Have you looked into what other public health authorities have to say about talc and ovarian cancer?
A. Yes.
Q. Would it be important for you to know that CDC does not list talc as a risk factor for ovarian cancer?
MS. PARFITT: Objection. Form.
A. I mean, it would be important to know, you know, various agencies, you know, CDC, whatever. I mean, you would like to know of many, many agencies.
But, again, you'd have to -- you'd have to see the quality of their judgment. I mean, what is their rationale? What are the studies they reviewed? What is the data available?
Just like as you said, what is the data available to me to make that judgment, what is data available to them? Just because they are the CDC doesn't mean that, you know -- yes, I would like to know their opinion, but then what is the underlying basis of their opinion?
Q. You're familiar with the CDC; correct?

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A. I'm very familiar with the CDC.
Q. It is an unbiased governmental entity; correct?
A. Well, it would depend on the opinion.
I mean, you know, we cannot say an entity is unbiased. It would depend what is the particular opinion -- you know, if the CDC provides vaccination. We have to look at the particular context.
Q. Are you aware that the CDC does not list talc as a risk factor for ovarian cancer?
A. Yes.
MS. PARFITT: Objection.
Q. Are you aware that the Mayo Clinic does not list talc as a risk factor for ovarian cancer?
A. I'm not aware of Mayo Clinic.
Q. You are aware of NIH; correct?
A. Yes. I'm funded by the NIH.
Q. Do you know that NIH does not list talc as a risk factor for ovarian cancer?
A. Yes. And I have been aware of, you know, changes in the past to their -- to their statements.
(Article entitled "Ovarian,

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Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ) - Health Professional Version marked Exhibit 15.)

MR. ZELLERS: Take a look at Deposition Exhibit 15.

MS. PARFITT: Thank you.

BY MR. ZELLERS:

Q. Deposition Exhibit 15 is a publication from the National Cancer Institute; is that right?

A. It is.

Q. National Cancer Institute is a leading health authority; is that right?

A. Yes.

Q. It's a leading cancer research institution in the world?

MS. PARFITT: Objection. Form.

A. Yes.

Q. Have you ever received a grant from the National Cancer Institute?

A. I've applied. I have not received any. I am applying again.

Q. They fund more cancer research than any organization in the world; correct?

MS. PARFITT: Objection.

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A. I don't know that particular number, but -- I just don't know that answer.

Q. Are you aware that the National Cancer Institute reviews the peer-reviewed literature as it relates to risk factors for ovarian cancer?

MS. PARFITT: Objection. Form.

A. Yes. And I don't know how updated they are. Based on the document you've provided me, they have four citations for perineal talc and ovarian cancer.

So, again, I'm not questioning the NCI's motivation, but I am -- I am raising, what is the quality of their judgment.

Q. Did you consider the CDC's determination that talc is not a risk factor for ovarian cancer in formulating your opinions?

A. Yes.

Q. Did you consider NIH's determination that talc is not a risk factor for ovarian cancer in formulating your opinions?

A. Yes. Because they did not have sufficient information, based on what they provided in their PDQs.

Q. Did you consider National Cancer Institute's opinion or conclusion that talc is not a risk factor for ovarian cancer?

MS. PARFITT: Objection.

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A. So the National Cancer Institute hasn't opined on that talc is not a causal -- you know, is causally linked to ovarian cancer. It has provided a listing of documents. It has not gone through any systematic process, that I'm aware of, of looking at the epidemiologic data systematically.

It has not provided any evidence of inflammation or lack thereof or migration or lack thereof or to even, you know, arrive at this causal hypothesis.

Q. Because it's important to look at both sides of an issue; correct?

A. Yes. I did look -- so I'm saying that I did look at this and my opinion --

Q. Did you --

MS. PARFITT: Please let him finish.

Q. Are you finished?

A. I'm saying I did look at this, and I'm aware of this document.

Q. Did you cite to the CDC in your report or references?

A. I don't -- I wasn't aware of the CDC.

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Q. Did you cite to the NIH in your report or your references?

A. I should have. And if it isn't, it is remiss.

Q. Did you cite to the National Cancer Institute in your report or references?

A. I have to look at it.

Q. The National Cancer Institute, in fact, has done an analysis, a very detailed analysis which we have marked as Exhibit 15 to this deposition; correct?

MS. PARFITT: Objection to form.

A. I don't think it's a detailed analysis of perineal talc and ovarian cancer.

There is how many lines? We can look at it and read it together. It's, you know -- it's 15 lines. And they have references 41 to 45, which is five references.

So I don't know it is a detailed analysis.

Q. National Cancer Institute, one of the things that it does is to review peer-reviewed literature as it relates to risk factors for ovarian cancer. Is that right?

MS. PARFITT: Objection. Form.

A. It does do that.

Q. All right. This document, this document that we're looking at from the National Cancer Institute, Exhibit 15, was updated in January of 2019; is that right?

A. Yeah. But it doesn't mean the review was updated, because it has no recent citations of studies that have been conducted.

Q. We --

A. We should look at the citation. Let's look at it, because we are discussing this document, so we should look at it in detail.

Q. Doctor, turn to Page 6.

A. No. Let me finish. I'm not finished with this document.

MS. PARFITT: Go ahead. Let him finish.

Q. Doctor, you have to answer my questions.

A. But I haven't answered it.

Q. My question is look at Page 6. Can you do that?

A. Okay.

Q. All right. Page 6 is a section on perineal talc exposure; is that right?

A. Yes.

Q. This is part of the National Cancer Institute's publication on ovarian, fallopian tube and primary peritoneal cancer prevention; is that right?

A. Yes.

Q. On Page 6, the first sentence under perineal talc exposure states, "The weight of evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer."

Is that right?

A. Based on what? Based on these 41 to 45 citations? Which are an incomplete listing of studies and an incomplete review of the evidence.

So I'm just stating that, yes, what is the underlying basis?

Q. Doctor --

MS. PARFITT: Wait. Let him finish. He's in the middle of a sentence.

A. What is the underlying basis of this opinion?

Q. Dr. Singh, my question is: Did I read the conclusion of the National Cancer Institute correctly?

MS. PARFITT: Objection.

A. I don't know if it's the conclusion, but, yes, you read that part of the statement correctly.

Q. Why would you rely on Health Canada, but not these other public health organizations?

MS. PARFITT: Objection. Misstates his testimony.

A. In fact, I did rely on the Health Canada when my report was conducted. So you see -- I relied on the quality of the review and the breadth of my review, which had hundreds of studies, the breadth of review of biological plausibility, the breadth of review of, you know, animal studies, applying the Bradford Hill framework, and then forming an opinion.

Q. How -- are you done?

A. No. I'm not done.

And the Health Canada Assessment came after that. And it so happened their methodology -- methodology -- methodology and opinions are consistent with mine.

So it's not that I'm relying on that. I'm just saying that they are consistent and they came to the same conclusions.

Q. What materials and analysis was done by

the CDC in determining that talc is not a risk factor for ovarian cancer?

MS. PARFITT: Objection. Form.

A. I don't have that.

Q. What materials were reviewed and relied upon by NIH in determining that talc is not a risk factor for ovarian cancer?

A. References 41 to 45.

Q. How do you know that that's all that the NIH and National Cancer Institute reviewed?

A. Because that's what they cite.

Q. Have you been privy to the complete review and analysis of the National Cancer Institute?

A. But you just stated that this was the complete review and analysis of the National Cancer Institute?

Q. I'm asking you: Do you know what specific studies and materials were reviewed and what analysis was done by NIH and by the National Cancer Institute?

A. Yeah. These are the studies that were reviewed.

Q. You are assuming that this is the entire analysis and review that was done by the

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National Cancer Institute; is that right?
MS. PARFITT: Objection. Form.
A. I'm not assuming anything. I'm assuming that, just as the conclusions that you are assuming are definitive, I'm also, you know, stating that these are the studies that they relied on to form those conclusions.
So we can't pick and choose, assess statement of the excerpt that you -- supports your opinion, but then not look at the underlying evidence base that supports that opinion.
Q. But we should consider all of that information; correct?
A. Yeah. And the studies underlying.
Q. And you did not consider the CDC's opinion in your report, did you?
A. I mean, CDC -- so let's just step back a little.
When I say CDC opinion, I mean, I'm looking at original studies. I'm looking at data in forming my opinion. I did look at what IARC considered and other agencies considered.
My opinion is based on my review and the methodology and I was, you know, obviously, taking into account what agencies say, but

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agencies' opinion is not necessarily the underlying basis of my causal opinion.
Q. Whether it's CDC, NIH, NCI or Health Canada; correct?
A. Yeah. I mean, they're informing. I want to look at their thinking and what is the quality of their judgment on this.
Q. You understand Health Canada has simply produced a draft assessment; is that right?
MS. PARFITT: Objection. Form.
A. Yes.
Q. We are at the beginning of the public comment period; is that right?
A. I don't know the timeline of that.
Q. Are you aware that Health Canada can take up to two years to take any action or no action at all?
A. Well, I mean, I was not asked a causal question on what to do about this. I was just asked a question on causality. And I'm not sort of -- I'm not privy to their process.
Q. How did you come to learn of the Health Canada Risk Assessment?
A. News, news documents.
Q. Were you involved in the risk

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assessment prior to its publication?
A. No.
Q. Have you submitted any comments to Health Canada?
A. No.
Q. Do you intend to submit any comments to Health Canada?
A. I don't know. I mean, it will depend on the timeline and I don't know what their timeline is and what my -- you know, I haven't -- I haven't thought about it.
Q. Outside of your litigation consulting, do you generally rely on draft assessments by regulatory agencies?
MS. PARFITT: Objection. Form.
A. Yes. I mean, you know, we look at draft assessments on regulatory. There's no reason not to.
Q. Have you ever cited a draft assessment by a regulatory agency in any study that you've published?
A. Oh, I've published 200 papers, and I can't recall, you know, which one, but I know that I have looked at draft assessments by the FDA.

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Q. Have you cited any?
A. I can't recall and tell you that. It's just something I can't recall.
Q. Are you familiar with the precautionary principle?
A. Yes.
Q. What is the precautionary principle?
A. It is to, you know, apply, as my understanding, is to warn when there is, you know, evidence of a hazard.
Q. That's your understanding of the precautionary principle?
A. Yeah.
Q. Do you understand that, as defined by Health Canada, a precautionary principle means taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and effect?
A. If you're stating -- well, let's get the document out before we --
Q. Sure. Take a look at deposition Exhibit 16.
(Document entitled "Health

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Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks - August 1, 2000" marked Exhibit 16.)
A. Okay. Can you point out which page?
Q. Sure. Take a look at Pages 8 and 9.
So we identify it for the record, Exhibit 16 is the Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risk; is that right?
A. Yes.
Q. If you go to Page 8 and 9, Section 1.3 are the underlying principles for Health Canada; is that right?
MS. PARFITT: Objection.
MR. TISI: You're looking at the wrong document. You're not looking at the draft assessment. You're looking at the --
MR. ZELLERS: Counsel, I am --
MR. TISI: But you identified something as something different than what it is.
MR. ZELLERS: I identified the document as Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risk. I'm reading the title of the document.
MR. TISI: Okay. I have it wrong. Go

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ahead.
MR. ZELLERS: That's okay.
A. Wherever we are.
Q. No problem, Doctor.
MS. PARFITT: We'll orient ourselves.
Q. Are we oriented?
A. Yeah. I know the document. But the page number.
Q. Look at Pages 8 and 9.
A. Okay.
Q. 1.3 are the underlying principles for Health Canada decision-making.
Do you see that?
A. Yes.
Q. They list out a number of underlying principles on Pages 8 and 9.
One of those is to use a precautionary approach; is that right?
A. Yes.
Q. If you then turn to Page 11, at the bottom, they define use of a precautionary approach; is that right?
A. Yes.
Q. Health Canada states in this document, which we've marked as Exhibit 16, "Use a

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precautionary approach. A key feature of managing health risk is that decisions are often made in the presence of considerable scientific uncertainty. A precautionary approach to decision-making emphasizes the need to take timely and appropriately preventative action, even in the absence of a full scientific demonstration of cause and effect."
Did I read that correctly?
A. Okay.
Q. Do you agree that the recommendation by Health Canada does not require a finding of causation like is required in a court; correct?
MS. PARFITT: Objection. Form.
A. But I mean, that's what they conclude, that there is a cause. We can look at the Health Canada document.
Q. Is a guiding principle of the Health Canada Decision-Making and Assessment to use a precautionary approach?
MS. PARFITT: Objection. Form.
A. Well, no. I mean, precautionary -- they are just defining a precautionary approach. But when they assess talc for its whatever, you know, the talcum powder products, their

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particular assessment clearly states it's causal. And we should open that document. We should not talk about it in hypotheticals.
Q. On what basis are you relying to state that Health Canada did not use a precautionary approach in assessing talcum powder?
MS. PARFITT: Objection. Form.
A. No. No. No. Let me answer that question.
You were asking about decision-making. Decision-making would be removal of talc, removal of that.
But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship.
Why aren't you bringing that document out? I mean, you can't talk about documents without documents.
Q. Dr. Singh --
A. Yeah.
Q. -- do you have any basis to state that, in evaluating talcum powder, Health Canada did not follow its underlying principle of using a precautionary approach?

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MS. PARFITT: Objection. Form. Misstates the evidence.
A. Yeah. But that does not preclude at arriving at a causal opinion. Just because you have a precautionary approach, you can still arrive at causal opinion, which they did.
So this is -- this principle is not inconsistent with their report on a causal opinion.
Q. The standard under a precautionary approach is that decisions can be made even in the absence of a full scientific demonstration of cause and effect; correct?
MS. PARFITT: Objection. Form.
A. That is a threshold, but that does not preclude the determination of cause and effect, which has been done already.
Q. Are you familiar with the Taher 2018 publication?
A. Taher. I don't know which one.
Q. T-A-H-E-R.
A. Yes.
Q. Are you familiar with that publication?
A. Yeah. It was cited in the Health Canada document.

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Q. Have you reviewed and analyzed that publication?
A. I mean, I reviewed it. I don't know if I analyzed it.
What do you mean by "analyzed"?
Q. You have not included it on your references or additional materials considered or updated materials; is that right?
MS. PARFITT: Objection.
A. It was part of the Health Canada. It should have been part, because it was part, in my mind, part of the Health Canada Assessment.
Q. Can you show me where --
A. Well, I haven't.
Q. -- the Taher publication is listed in your updated materials which we marked as Exhibit 6?
MS. PARFITT: For the record, we created this list, Mr. Zellers, and part of the Canadian, just for form, and you can inquire.
MR. ZELLERS: That's okay.
MS. PARFITT: But since we did create Exhibit No. 6, additional materials, we had included, I will tell you, we had given him Taher. He may have found it himself.

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A. No.
Q. Hold on. Stop. Stop.
A. Sure.
Q. Just so we're clear, the updated materials list is a list that was created by plaintiffs' counsel; correct?
MS. PARFITT: It was based upon materials that we had either sent or we had sent that he also had; correct.
MR. ZELLERS: This Exhibit 6 is a list of materials that were provided by plaintiffs' counsel to Dr. Singh, understanding that Dr. Singh has testified that he independently had access to some of the materials.
MS. PARFITT: Correct. Including Taher.
THE WITNESS: Yeah. And some of them, I added, such as some of the published articles and Health Canada.
BY MR. ZELLERS:
Q. You have read the Taher 2018 manuscript; is that right?
A. I mean, I read the -- yeah, I mean, primarily, I read their assessment in Health Canada.

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MR. ZELLERS: Deposition Exhibit -- well, strike that.
Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right?
A. Yes.
Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right?
A. Yes.
(Document entitled "Systematic Review and Meta-Analysis of the Association between Perineal Use of Talc and Risk of Ovarian Cancer" marked Exhibit 17.)
BY MR. ZELLERS:
Q. The Taher article is what we have marked as deposition Exhibit 17; is that right?
MS. PARFITT: Thank you.
MR. TISI: Is it Thayer or Taher?
A. It is Taher, T-A-H-E-R.
Q. Did you have access to the Taher 2018 article before it was published?
A. Yes.
Q. How did you have access to the Taher

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2018 article?
A. Yeah. I requested access from the attorneys, if they had it. They provided it.
Q. So plaintiffs' attorneys provided you with access to the article we've marked as Exhibit 17 prior to its publication; is that right?
A. Yeah.
MS. PARFITT: Objection.
A. I don't know if it has been published yet.
Q. Did you have access to the appendices or supplemental tables referenced in the Taher publication?
A. Yes, I did.
Q. In your epidemiologic -- strike that.
Is the Taher publication, which we've marked as Exhibit 17, is that peer-reviewed?
A. It's peer-reviewed, and I assume that it's going to be published. And it was reviewed by Health Canada. So I mean, it is peer-reviewed, is my understanding.
It is -- I don't know the exact status of that manuscript.
Q. What organization has peer-reviewed the

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Taher publication, Exhibit 17?
A. So I don't -- yeah, again, I take it -- I don't know the status of that manuscript, where it is.
Q. You do not know, one way or the other, as to whether the Taher publication, Exhibit 17, has been peer-reviewed; is that right?
A. Yeah. Whether it's been accepted or submitted or -- I don't know.
Q. Are you finished?
A. I don't know the status. I'm trying to say that.
Q. In your epidemiological work, outside of litigation, do you rely on articles that have not been peer-reviewed?
A. Yes. Several times, we rely on articles. Several times, we actually request articles if it's key to something that we are working on and we know that a particular investigator is active in that area and he may have.
So, yes, we actually -- sometimes we request that. And the majority of the times people don't provide their work until it's published. But sometimes we get it. Yeah.

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Q. Why did you rely on this article, Taher, Exhibit 17?
MS. PARFITT: Objection to form.
A. I mean, when you say I relied on, I mean, I reviewed the, again, Health Canada Assessment. So none of this is in isolation.
I mean, this is just a part of, you know, the body of evidence. You know, my testimony relies on -- and my report relies on the evidence cited there.
This is, you know, another meta-analysis that, you know, I reviewed the evidence in slightly different ways and came to the same conclusions and, you know, also did a causal analysis. So it's sort of, you know, you have to review what evidence comes out.
If another meta-analysis comes out tomorrow, then I would review it.
Q. Do you know the source of funding for this publication?
A. I don't know. I mean, Health Canada or something else, I don't know that. I can't answer that question.
Q. You're assuming that Health Canada is the source of funding for this publication?

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A. I don't know. I shouldn't answer that.
Q. Do you know the credentials of the authors of the Taher 2018 publication, Exhibit 17?
A. I have no idea.
Q. Do you personally know any of the authors that are listed?
A. No.
Q. Do you know whether or not any of the authors of the Taher publication, as listed out on the first page of Exhibit 17, have conflicts of interest?
MS. PARFITT: Objection.
A. Not that -- I didn't -- again, I read the article. I don't know what their, you know, declarations are. Yeah.
And it does say it was conducted under contract to Health Canada. So it seems like the funding source is Health Canada. And let's look at their source of funding.
Q. Doctor, we'll never finish if you want to just go through and look at things.
My specific question is whether or not you know whether or not any of the authors have conflicts of interest?

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MS. PARFITT: Objection.
A. That's a very vague and broad question. I mean, conflicts of interest as it relates to what?
Q. Do you know?
MS. PARFITT: Objection. Form.
A. As it relates to what?
Q. You told me you don't know any of the authors; right?
A. Yeah.
Q. I've now asked you if you know if any of the authors had conflicts of interest.
A. And I'm saying that I'm reading the article and I'm reading their declaration, and that's the only way to find out that they have conflicts of interest, right.
Q. I should be more precise.
A. Yeah.
Q. Of your own personal knowledge, do you know whether or not any of the authors have conflicts of interest?
A. That's a separate --
MS. PARFITT: Objection.
A. So what I'm trying to say is, you know, when you ask about conflicts of interest, if you

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want to ask about my article, you'd have to go and read the article and see that, what is stated there.
So that's what I'm trying to answer when you ask. I'm trying to be honest and truthful about my answers.
MR. KLATT: Objection; nonresponsive.
MR. ZELLERS: Move to strike as nonresponsive.
THE WITNESS: I didn't understand the question.
MR. LOCKE: We all have questions to ask this witness. We're not going to make the seven hours with these answers that do not answer the questions.
THE WITNESS: Maybe I'm not understanding the question. I'm sorry. It's not that I'm trying to --
Q. Dr. Singh, the authors of the Taher paper concluded that the evidence suggests that asbestos contamination does not explain the positive association between perineal use of talc powder and ovarian cancer; is that right?
A. Where do you --
Q. Take a look at Page 41, the last

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sentence. And I'll read it. Have you found Page 41 of Exhibit 17?
A. 41?
Q. Yes. Page 41. Do you have that?
A. Yeah. Yeah.
Q. The very last --
A. Yeah. I'm looking at it.
Q. Tell me if I read this correctly. "The similarity of findings between studies published prior to and after this point suggest asbestos contamination does not explain the positive association between perineal use of talc powder and risk of ovarian cancer."
Did I read that correctly?
A. Yes.
Q. Do you disagree with the authors on that point?
A. Let me just read it.
Well, I mean, to the extent that they are aware that asbestos does not contaminate -- talc is not contaminated with asbestos, I do agree. But, again, I have, you know, obviously more information on that.
Q. On Page 25 of Exhibit 17, the Taher 2018 article, is a table entitled "Summary of

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Evidence for Each of the Hill Criteria of Causation as Applied to Perineal Application of Talc and Ovarian Cancer."
Is that right?
A. Yes.
Q. One of the Hill criteria is consistency; is that right?
MS. PARFITT: Objection. Form.
A. Yes.
Q. Looking at authors' statement on consistency, it states, "15 out of the 30 studies reported positive and significant associations."
Is that right?
A. Yes.
Q. 15 out of 30, that's 50 percent; is that right?
MS. PARFITT: Objection. Form.
A. Yeah. But I have -- I disagree with their interpretation of consistency as being, you know, statistically significant. I mean, you know, my assessment is, you know, estimates towards greater than one.
MR. ZELLERS: Move to strike as nonresponsive.
Q. My question was: 15 out of 30 is

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50 percent?
A. Yes.
MS. PARFITT: Objection. Let me object, please.
Q. That's no better than a coin toss; correct?
MS. PARFITT: Object to the form.
A. It is 50 percent.
Q. Would you say that 15 out of 30 means there are consistent results across studies?
A. Well, I mean, again, my definition of inconsistency, as noted in my report, is different from theirs.
Q. These are just the case control studies; is that right?
A. When you say -- they just say 30 studies. Yeah.
Q. These are case-control studies; is that right?
MS. PARFITT: Objection. Form.
A. Well, they're both, right? Case control and core.
Q. The authors in Taher also recognize that there's no consistent dose-response across studies; is that right?

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MS. PARFITT: Objection. Form.
A. Well, let me look at the dose-response section.
Q. Page 21. And I'm looking at the very last sentence above Section 3.3.2.
A. Tell me, which page number?
Q. Sure. Page 21.
A. We do have to slow down so that I can move between pages, if you don't mind.
Yes.
Q. This is in the section "Evidence from Human Studies"; correct?
A. Okay.
Q. Is that a yes?
A. Yes.
Q. The statement by the authors, "When conducted, findings from trend analyses were not consistent."
Is that right?
A. The last line?
Q. Yes.
A. Yes. But the criteria for dose-response is just exposure-response gradients. I mean, it doesn't, you know, say as -- even in -- I state in my report, there's no

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consistent evidence. There are studies that provide dose-response and other studies that don't.
Q. You currently work for the University of Massachusetts; is that right?
A. Yes.
Q. You work for both the medical school and the medical center; is that right?
A. Yes.
Q. Are you aware that the University of Massachusetts does not claim that talcum powder causes ovarian cancer?
MS. PARFITT: Objection. Form.
A. I don't know what -- they're listed on their website. I'm not sure they provide any information sheet that I am aware of.
(Printout entitled "Ovarian Cancer: Risk Factors" marked Exhibit 18.)
BY MR. ZELLERS:
Q. Take a look, if you will, at Deposition Exhibit 18.
MR. TISI: What is 16?
MR. ZELLERS: Exhibit 16 was the Health Canada Decision-Making Framework. It's right here.

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MR. TISI: Oh. I have that, Counsel. Thank you.
BY MR. ZELLERS:
Q. Have you had an opportunity, Dr. Singh, to review Deposition Exhibit 18?
A. Yes.
Q. This is a website from the University of Massachusetts Memorial Healthcare; is that right?
A. Yes.
Q. Are you familiar with the website?
A. I mean, overall website, but not this particular document.
Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.
Do you see that?
A. Yes.
Q. The statement is, "It's not clear if using talcum powder on the genital area raises the risk for ovarian cancer. Talk with your healthcare provider if you decide you want to use talcum powder."
Did I read that correctly?

A. Yes, you did.
Q. Why doesn't your institution list talc exposure as a risk factor for ovarian cancer?
MS. PARFITT: Objection. Misstates the evidence.
A. So, yeah, I mean, first of all, this is -- I've seen this the first time here, but as you can see, again, this is -- we have to go to Page 3 of 4 and it's medical reviewers and they are, you know, basing their opinion on whatever. This was done in 2013.
So it depends on the -- it's not that, you know, my medical, you know, employer is listing it. Obviously, it's listed there.
And but it's based on the quality of the evidence. This was reviewed on 2016, and it was reviewed by, as you see, the credentials of -- did they review the -- did they review the biological evidence? Did they have any additional information?
So I don't disagree with their opinion, I'm just saying.
Q. Dr. Singh, do you recommend to your own patients that they avoid talcum powder use?
A. Now, I do.

Q. When did you begin doing that?
A. Last year.
Q. Do you ask them if they use talcum powder as part of a routine screening?
A. In people that -- sorry.
In patients that I talk about ovarian cancer.
Q. Is that something that you began doing over the past year?
A. I would say sometime last year.
Q. What about patients with a long history of use? Do you consider them at elevated risk of developing cancer?
MS. PARFITT: Objection. Form.
A. So I haven't thought about it that way. I mean, you know, when that discussion about ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.
Q. Have you ever recommended prophylactic surgery to remove the fallopian tubes and ovaries that you think -- patients that you think may have had long-term exposure to talc?
MS. PARFITT: Objection. Form.
A. No.
Q. Causation. On Page 66 of your report,

take a look at Exhibit 2 or Exhibit 10, whichever is easier for you.
A. Page 66?
Q. Yes. Your conclusion.
A. Yes.
Q. You state that peritoneal use of talcum powder products can cause ovarian cancer; correct?
A. Yes.
Q. Is it your opinion that it does cause ovarian cancer or just that it can?
MS. PARFITT: Objection to form.
A. I don't know the semantics of what would be -- if -- semantics of can and does. I mean, you can explain to me. Maybe my English is not as good as yours.
Q. What type of exposure causes ovarian cancer?
A. Perineal application. So I mean, are you asking specific to talc?
Q. Yes. With respect to talc exposure, what type of talc exposure causes ovarian cancer?
MS. PARFITT: Objection. Form.
A. You know, perineal application of talc can, you know, use of talc.

Q. What types of -- strike that.
What types of talcum powder cause ovarian cancer?
MS. PARFITT: Objection. Form.
A. So, again, I -- I -- my causal question was the use of talcum powder products and ovarian cancer. I did not disaggregate between X and Y and Z in terms of, you know, this type of talcum powder product.
Q. What type of ovarian cancer does talcum powder cause?
MS. PARFITT: Objection. Form.
A. Talcum powder products are, you know, causally linked to the development of ovarian cancer, but the link is strongest for serous epithelial ovarian cancer.
Q. Any other types of ovarian cancer that you believe talcum powder causes?
MS. PARFITT: Objection. Form.
A. You know, other studies have provided, you know, causal links to borderline, you know, other tumors. But, you know, it's mainly the epithelial ovarian cancer.
Q. What dose of talcum powder is required to cause ovarian cancer?

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MS. PARFITT: Objection. Form.
A. I examined, you know, the causal link between talcum powder products and ovarian cancer as the data was available in the available studies. You know, I could not -- there was no -- I mean, there was data on dose-responsiveness, and we can discuss that.
But, you know, I don't know if it's a single application or it's 20 years. I mean, it is regular use and that would cause it.
Q. It's correct that you have not evaluated specifically what dose of talcum powder is required to cause ovarian cancer; correct?
MS. PARFITT: Object to form.
A. Yeah. I mean, I don't know a specific dose that would cause ovarian cancer.
Q. What was your methodology for concluding that talc causes ovarian cancer or, I guess to be more precision, serous ovarian cancer?
A. Yeah. I mean, mainly --
MS. PARFITT: Objection.
A. Yeah. Epithelial ovarian cancer.
Q. What was your methodology?
A. So, yeah, I did, you know -- so prior

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to that, I was aware of systematic reviews and other reviews in this area.
So I, as a broad -- you know, we should look at the methods section of this report.
Do you want to look at the methods?
Q. Well, if you have to. I mean, my question was just simply: What was your methodology for concluding that talc causes epithelial ovarian cancer?
MS. PARFITT: Dr. Singh, anytime you need to consult your report.
A. Yeah. I mean, the methodology was, you know, gathering lines of evidence. You know, assessing for relevance, reliability and, you know, again, assembling other lines of evidence for animal, human studies, the constituents of talc. And then assessing them within an analytic framework, the Bradford Hill, and then, you know, providing a weight-of-evidence opinion based on my professional judgment.
Q. In other cases in which you've been retained as an expert, you've conducted a meta-analysis of the available data to reach a conclusion about the relative risk; correct?
A. I have.

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Q. You did not conduct a meta-analysis here; is that right?
A. Yes. And I -- partly pragmatic reasons. Partly, there were so many other meta-analyses that I, you know -- although I would have done things a little bit differently, and I just didn't feel the need for one more meta-analysis that would be informative.
Q. What was your methodology for focusing on certain studies or excluding other studies?
A. So I'm not aware that I excluded certain studies, because I, as I compare, I have included all the epidemiologic studies that are here. There's always a possibility that once, you know, when you do a review, that you may have.
But, you know, I included all the relevant case-control studies and the cohort studies and the systematic review and meta-analysis that I identified.
And, yeah, I mean, I may have weighed studies differently based on their quality, validity and reliability.
Q. That's how you tried to make a distinction?

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A. Yeah.
Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation?
MS. PARFITT: Objection. Form.
A. Yeah. I mean, the standard for causation, you know, is -- at least I was applying the same standard.
Q. Are you familiar with the FDA analysis of the Bradford Hill factors and that they have concluded that causation is not established with respect to talc and ovarian cancer?
MS. PARFITT: Objection. Misstates the evidence.
A. I am aware of a FDA letter. I'm not sure that there's a Bradford Hill analysis. And if you can share that with me, that would be --
Q. Please review Deposition Exhibit 19.
(Letter dated April 1, 2014 marked Exhibit 19.)
MS. PARFITT: Thank you.
BY MR. ZELLERS:
Q. Deposition Exhibit 19 is a letter from the FDA to Sam Epstein, dated April 1st of 2014; is that right?

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A. Yes.
Q. And when I say "dated," there's a stamp at the top that says April 1, 2014; correct?
A. Yes.
Q. Have you reviewed this FDA analysis before today?
A. Yes. I have reviewed the letter. Yeah.
Q. On Page 4 of the FDA document, at the bottom, do you see that?
A. I do.
Q. The FDA noted that selection bias and/or uncontrolled confounding result in spurious positive associations between talc use and ovarian cancer; is that right?
MS. PARFITT: Objection. Form.
A. Yes. That's what they conclude.
Q. The FDA notes a lack of consistency in the study results; is that right?
MS. PARFITT: Objection.
A. Yes. And this was conducted in, I don't know, 2014, 2013.
Q. The FDA specifically states, "Results of case-control studies do not demonstrate a consistent positive association across studies";

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is that right?
A. Yes. That's what they state.
Q. The FDA also states that, "Dose-response evidence is lacking"; is that right?
MS. PARFITT: Objection.
A. Where is that? I'm sorry.
Q. Look at Paragraph 3 at the bottom of Page 4.
A. Yes.
Q. The FDA further concludes that, "A cogent biological mechanism by which talc might lead to ovarian cancer is lacking"; is that right?
MS. PARFITT: Objection to form.
A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm just trying to be -- that's what I reviewed.
Yes, it does say that there's no biological mechanism.
Q. You reviewed -- or strike that.
In addition to the FDA looking at and applying the Bradford Hill criteria, IARC does that as well; is that right?

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MS. PARFITT: Objection. Form.
A. So just to clarify, where do they say they apply the Bradford Hill in this document?
Q. You're familiar with the Bradford Hill criteria; is that right?
A. Yes. I use it, but in this FDA document, where does it state they apply the --
Q. It is one of the criteria for consistency across studies. Is that a Bradford Hill criteria?
A. But exactly they don't go through all of them. So I don't know if they did a Bradford Hill. So how can I just assume that? They don't talk about, you know, specificity. They don't talk about strength of association. So I can't assume that they're applying Bradford Hill.
Q. IARC did address the Bradford Hill considerations; is that right?
A. Yes. In the year 2005. That was around 15 years ago.
Q. IARC rejected classification of talc as carcinogenic and, instead, assigned it to the classification of possibly carcinogenic to humans; is that right?
MS. PARFITT: Objection. Misstates the

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evidence.
A. So, again, you know, just clarifying that this was done in 2005, with evidence that has accumulated since then. And I wouldn't classify it -- I have served on IARC panels, and I'm very familiar with their process. They don't reject anything. They classify drugs in the particular categories that they're supposed to be.
So it was actually classified as possibly carcinogenic.
Q. Take a look at Exhibit 20.
(IARC Classifications marked Exhibit 20.)
BY MR. ZELLERS:
Q. Deposition Exhibit 20 are the IARC classifications; is that right?
I'm sorry. Did you answer the question?
A. Yes. Sorry.
Q. That's okay.
A. Yes.
Q. All right. It lists out, starting with Group 1, carcinogenic to humans, down to Group 4; is that right?
A. Yes.

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Q. There are 120 agents that have been determined by IARC, the International Agency for Research on Cancer, as Group 1 agents, carcinogenic to humans; is that right?
A. Yeah. That includes asbestos, many others.
Q. That is the only category in which IARC finds sufficient evidence in humans; correct?
A. No. To clarify, they have -- it may be in my report, that they have a particular way of defining that category. And it may not be just sufficient evidence in humans. They may be something else. If I can look back at my report.
Q. Well, if it's in your report, it's in your report. And we can all read that.
My question to you is: Group 1 is a category where IARC has determined that there is sufficient evidence in humans to classify an agent as carcinogenic; is that right?
MS. PARFITT: Objection. Misstates Dr. Singh's testimony.
A. I mean, do I get time to --
Q. Doctor, I only have seven hours here.
So go to Exhibit 20. I'll make this quick.
Do you see Exhibit 20 in front of you?

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A. Yeah.
Q. This is the IARC classifications; is that right?
A. Okay. Mm-hmm.
Q. Group 1 states, "Carcinogenic to humans."
A. Yes.
Q. Do you see that?
A. Yeah.
Q. All right. Group 2A, there are 82 agents that are probably carcinogenic to humans; is that right?
A. Yes.
Q. IARC is certainly capable of reaching a decision that something is a known or probable carcinogen; is that right?
MS. PARFITT: Objection.
A. Yes. I mean, 15 years ago, yes, based on the evidence.
Q. It has placed at least 200 agents in Group 1 or Group 2A; is that right?
A. Yes.
Q. There's only one agent in Group 4, probably not carcinogenic to humans; is that right?

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A. Yes.
Q. So out of the 1,000 agents that IARC has reviewed, it has placed only one agent in Group 4, probably not carcinogenic; is that right?
A. Yeah. But 499 are not classifiable as it relates, so.
Q. IARC doesn't even have a Group 5, not carcinogenic, does it?
A. Well, I mean, all the -- once it's probably not carcinogenic, it's not carcinogenic.
Q. The best that IARC can state is that an agent is probably not carcinogenic to humans, which is Group 4; is that right?
A. Yes.
MS. PARFITT: Objection.
Q. All right. As with -- strike that.
With genital talc, the IARC group 2B designation is based on limited evidence in humans; is that right?
MS. PARFITT: Objection.
A. Yes. There was some animal consideration. There were some biological mechanisms, but, again, in 2005, and as I state in my report, which I have, and there have been

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multiple studies since then. And that, you know, that they should be revisited.
Q. That means IARC cannot rule out chance, bias or confounding with reasonable confidence; correct?
A. Based on the data they had at that time.
Q. What else is in 2B, possibly -- strike that.
What else is in class 2B, possibly carcinogenic? Are you familiar with Ginkgo biloba?
MS. PARFITT: Objection to form.
A. I know the name.
Q. Are you aware that that's classified as a 2B agent by IARC?
A. I don't know. I mean, you know, they also classify as it relates to exposure. So I haven't reviewed Ginkgo biloba to be able to answer the question.
Q. Pickled vegetables, 2B; is that right?
A. How do I know? Show me.
Q. Occupational --
A. That's what you're saying.
Q. -- carpentry and joinery, 2B? Are you

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aware of that?
A. Again, this is 2015. And, you know, yes. I don't know I'm aware of that. I mean, you can't put words in my mouth that pickle -- how do I know that?
Q. There's no chance of my putting words in your mouth. IARC can change its classification for a substance; is that right?
A. It does. I mean, from what I understand.
Q. It has not changed its Group 2B classification since it determined that talc was a 2B agent; is that right?
MS. PARFITT: Objection. Form.
A. It has not carried out an assessment since 2005, that I'm aware of.
Q. Has IARC changed its group 2B classification?
A. No --
MS. PARFITT: Objection.
A. -- and as far as I'm aware, no assessment has been carried out.
Q. Bradford Hill, strength of association is one of the criteria; is that right?
A. I don't consider them criteria.

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There's overviews. I think -- I'm just picking the terms. I mean, they're overviews of Bradford Hill. Doesn't list them as criteria, because criteria implies a list of things that you can pick and choose from.
Q. You would call them what?
A. Overviews. Actually, that's what he calls them.
Q. Overviews. Strength of association is a Bradford Hill overview; is that right?
A. Yes.
Q. Epidemiologists consider a 1.3 odds ratio in case-control studies to be a weak or modest association; is that right?
MS. PARFITT: Objection. Misstates the evidence.
A. No. I mean, again, strength of association based on -- depends on the study question at hand, the study design, and, you know, the quality of the underlying data. So strength of association, in and of itself, does not provide any -- any -- any sort of -- any answer to the causal question. Again, I'll go back to my report, because I have to go back to my report.

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Q. Doctor, I'm asking you questions.
My question is: Epidemiologists consider a 1.3 odds ratio in case-control studies to be a weak or modest association; correct?
MS. PARFITT: Objection. Misstates the evidence and the science.
A. Not the epidemiologists that I contacted. You know, we look at various, you know -- as I state in my report, you know, you can have modest associations and you can have a relative risk of one that are lower, and if you go to a low-prevalence population, and then remove competing risk factors, those can be attenuated.
So the epidemiologists that I interact with, and we don't look at this as weak or modest or high. We just look at it in the whole causal framework.
Q. Can you point to any peer-reviewed literature on talc and ovarian cancer that states that 1.3 odds ratio is a strong association?
A. Again, that's not -- I'm not looking at talc at 1.3 is a strong association. I'm stating that, yeah, I can't point to the talc literature that states that.

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Q. IARC does not refer to this as a strong association; correct?
MS. PARFITT: Objection. Form.
A. I don't know what -- the particular objective or qualifier they use. I mean --
Q. FDA doesn't refer to this as a strong association, do they?
MS. PARFITT: Objection to form.
A. Again, you have to sort of just show me where they are, and I'll agree with it.
Q. Have you seen any statement from IARC that there is a strong association between genital talc use and ovarian cancer?
A. I don't recall that particular phrase.
Q. All right. The National Cancer Institute doesn't refer to this as a strong association; correct?
MS. PARFITT: Objection to form.
A. I don't recall that particular objective.
Q. Do your opinions on strength of association apply equally to all forms of ovarian cancer?
MS. PARFITT: Objection. Form.
A. Again, I'm -- you know, my opinions are

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not -- again, we can parse this out. I mean, I was just looking at the causal question. Is talc causally related to the development of ovarian cancer?

And, you know, most of the evidence that I examined were -- was provided in terms of serous epithelial cancer, and --

Q. I thought you told me that your methodology was to look at the Bradford Hill overview factors; is that right?

A. Yeah.

Q. All right. And one of those factors is strength of association; is that right?

A. Yes.

Q. And that's a factor that you looked at; correct?

A. Yes.

Q. Do your opinions on strength of association apply equally to all forms of ovarian cancer?

MS. PARFITT: Objection. Form.

A. Well, I did not disaggregate my, you know, opinion by histologic subtype.

Q. You cite to the Langseth paper; is that right?

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A. I do.

Q. You state that the authors in Langseth 2008 found an odds ratio ranging between 1.12 to 1.4, depending upon the type of study design. Is that right? This is on Page 22 of your report.

A. Okay.

Q. Langseth, in fact, rejects causation and says more study is needed; correct?

MS. PARFITT: Objection. Form.

A. I don't know why you have stated they reject causation. Show me that statement in that article.

Q. Take a look, if you will, at Deposition Exhibit 21.

(Article entitled "Perineal use of talc and risk of ovarian cancer" marked Exhibit 21.)

MS. PARFITT: Thank you.

MR. ZELLERS: Mm-hmm.

BY MR. ZELLERS:

Q. Deposition Exhibit 21 is the Langseth 2008 meta-analysis that you cite in your report; is that right?

A. Yeah. It's one of the meta-analyses.

Q. Turn to Page 359 of Exhibit 21. Tell me when you have that.

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A. Yeah.

Q. "Proposal to research community." Do you see that?

A. Yes.

Q. Tell me if I read this statement by the authors correctly.

"The current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk. Experimental research is needed to better characterize deposition, retention, and clearance of talc to evaluate the ovarian carcinogenicity of talc."

Did I read that correctly?

A. Yes.

Q. You're drawing conclusions from this study that are broader than the study authors' own conclusions; is that right?

MS. PARFITT: Objection.

A. I didn't draw. So you were asking me that whether I drew a single conclusion from the Langseth. I mean, there are -- I think I cite all the meta-analyses first, and then -- so I'm not just drawing inferences from there.

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And the authors, as far as I am aware, A, there have been several other studies published since then. This is 2007. So we have 12 years and several publications. And, B, the authors themselves have provided opinions that they are causally related. Dr. Siemiatycki, as far as I'm aware.

Q. Did you cite this paper in your report?

A. Yes.

Q. The authors in this paper state that the current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk; is that right?

MS. PARFITT: Objection. Misstates the evidence in this case. The science and testimony.

A. It says the current body of evidence. This is current as of two thousand and whenever.

Q. This is the paper. 2008, Exhibit 21, that you relied on --

A. Yeah.

Q. -- and cite in your report; correct?

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A. This is not the only --
MS. PARFITT: Objection. Form.
A. -- paper. I cited on 2017, 2018.
Q. Go to the acknowledgments section.
Do you see the acknowledgments off to the left?
A. Yes.
Q. The authors are IARC members; is that right?
A. Yes.
Q. The authors of this paper, Langseth?
A. Yes.
Q. Another overview factor of Bradford Hill is consistency; is that right?
A. Yes.
Q. The literature does not show a consistent association between talc use and ovarian cancer; right?
MS. PARFITT: Objection to form.
A. I disagree.
Q. The cohort studies do not show an association between talc use and ovarian cancer; correct?
MS. PARFITT: Objection to form.
A. I disagree. The cohort studies show

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significant -- you know, increased risk, which is in the same direction as the case-control studies, which, as several of the authors, such as Penninkilampi and others and me, interpret as evidence of consistency.
Q. The cohort studies are what?
A. I'm sorry?
Q. List out the cohort studies for us.
A. Penninkilampi is a meta-analysis. They are an interpretation of the cohort studies.
Q. You told me before that to do a proper analysis, you have to go and look at the individual studies; is that right?
A. I do. I did.
Q. And you went and you reviewed the cohort studies; is that right?
A. Yes.
Q. And it's your testimony that those cohort studies do show an association between talc use and ovarian cancer. Is that your testimony?
A. So I reviewed the cohort studies in line with 30 case-control studies in line with 70, you know -- sorry -- seven other meta-analyses and, you know, synthesizing the

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overall evidence, my testimony is that the cohort study estimates are in line with the case-control evidence and provide evidence of consistency.
Q. The cohort studies themselves, looking just at those studies, and I'm going to ask you about the others --
A. Sure, sure.
Q. -- do not show a consistent association between talc use and ovarian cancer; correct?
MS. PARFITT: Objection. Misstates the testimony.
A. So that's not the way I look at evidence. I look at everything. That's what you want to look at. You can look at it.
I just look at evidence, you know, whatever is out there. So I didn't look at cohort studies in and of themselves.
And that's why we do systematic reviews. That's why we do meta-analyses, because you want to look at everything at the same time.
Q. You did not look at the cohort studies individually; correct?
A. I did. And they're in my report.
Q. If you looked at the cohort studies

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individually, they do not show a consistent association between talc use and ovarian cancer; correct?
MS. PARFITT: Objection. Misstates the evidence.
A. So how can you look at individually and answer questions about consistency? To answer questions about consistency, you have to look across studies. And when you look across studies, you have to bring all studies.
And that's when you can opine on consistency.
Q. Doctor, my question relates just to the cohort studies.
A. I understand.
Q. The cohort studies do not demonstrate an association between talc use and ovarian cancer; correct?
MS. PARFITT: Objection. Misstates the evidence.
Q. Just the cohort studies.
MS. PARFITT: Objection. Misstates the evidence.
A. First of all, you know, they do increase -- an increase of serous epithelial

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ovarian cancer in one of them, and cumulative evidence from cohort studies shows an excess risk of ovarian cancer which is not statistically significant.

Q. Hospital-based, case-control studies collectively do not show an association between talc use and ovarian cancer; correct?

MS. PARFITT: Objection. Misstates the evidence.

A. That is incorrect, because hospital-based, case-control studies also show an association between talc use and ovarian cancer which is not, you know -- and I would have to look again. Please bring out the studies, because I want to look at some of the studies before I, you know, provide specific -- you're asking very specific questions about hospital-based studies, so I have to look at the studies.

Q. If you can't answer a question, tell me you can't answer it. But my question is, hospital-based, case-control studies collectively do not show an association between talc use and ovarian cancer; correct?

MS. PARFITT: Objection. Misstates the

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evidence.

A. No. I disagree. And, again, I'd have to -- can we pull the Penninkilampi paper?

Q. Doctor, I'm going to ask you about that paper.

A. No. But then how can I answer questions?

Q. I need you to answer my questions.

If you can't answer a question, then tell me you can't answer the question.

A. I'm willing to answer the question. Just bring me the evidence so that I can look at it.

I'm sorry. I'm trying my best.

Q. In your report, you state that hospital-based, case-control studies may be less susceptible to selection bias than population-based, case-control studies; correct?

A. Where do I state that?

Q. Look at your report on Page 54, Paragraph 8.

A. Actually, I state entirely the opposite. I state that the population-based studies may have --

Q. So --

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MS. PARFITT: Wait. Are you in the middle?

A. Yeah. That's incorrect. It should be the population-based case studies. That's my -- you know, that's a misstatement on my part.

Q. So you need to amend your report?

A. Yeah. Yeah.

Q. So if we go to Page 54 --

A. Yeah.

Q. -- Paragraph 8, you state that it's an error when you state, "As opposed to hospital-based controls, which may be less susceptible to selection bias, the population-based, case-control studies have consistently showed a higher estimate of increased risk of ovarian cancer associated with talc use."

A. Yeah. And I was applying the less susceptible to the population-based statement.

Q. How do you need to correct this statement?

A. I don't know how, you know. Yeah, it would be as opposed to hospital-based controls, population-based, case-control studies may be less susceptible to selection bias.

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Q. You believe that population-based studies may be susceptible to less selection bias?

A. May be less susceptible.

Q. Take a look at Exhibit 21. That's the article we looked at a few minutes ago.

Do you see that?

A. That's the Langseth?

Q. Yes. The Langseth article.

Do you see that?

A. Yes.

Q. Take a look under the hospital-based studies.

Do you see that on Page 359?

A. Yes.

Q. You are the one who cites this paper and relies on it; is that right?

A. Yes.

Q. If we look at pooled odds ratio for hospital-based studies --

A. Mm-hmm.

Q. -- the odds ratio is 1.2 and the confidence interval is a .92 to 1.36; is that right?

A. Yes.

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Q. That means that it may or may not be -- show an association between talc use and ovarian cancer. The pooled result; is that right?
MS. PARFITT: Objection to form.
Q. Given that confidence interval.
MS. PARFITT: Objection to form.
A. Yeah. Again, this is -- you know, at that time. I don't know what studies have been added. We can look in the new paper, which I'm not sure why it's not been brought up.
But, yes, it does show an excess risk, not statistically significant, consistent with the population studies.
Q. All right. Hospital-based control studies, you're more likely to be comparing hospitalized patients to hospitalized patients; is that right?
A. Yes. That's why they're hospital based.
Q. Population-based studies, you're more likely to be comparing ill people to healthy people; is that right?
A. Yeah. Your source of control. I mean -- well, it depends. How do you know if it's ill people? If you are sourcing from the

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population in both, it's a population-based study.
Q. Population-based, case-control studies, the ones that you look at only show a weak association between talc use and ovarian cancer; is that right?
MS. PARFITT: Objection. Misstates the evidence.
A. I think we went about that weak. I don't believe that they are weak. We went through that.
Q. That's your --
A. Yeah. My opinion is that they're not weak evidence.
Q. Isn't the absence of an association in the cohort studies especially significant in that the study design reduces the likelihood of recall bias?
MS. PARFITT: Objection to form.
A. Yes. I mean, it is important to look at recall bias in the cohort studies. But the study design introduces several elements of other bias for an outcome such as ovarian cancer.
You know, I'm answering your question, because you asked about bias. It introduces

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behavioral change bias, which attenuates towards the null. It induces an element of misclassification of exposure, which goes towards null. It limits the duration of assessment, which, you know, limits assessment. So it doesn't have power to suggest.
So, yes, recall bias is a feature that is better assessed in the cohort studies, but recall bias, for exposures that are daily use, such as talc, are less likely, you know, to be in play. Recall bias -- let me finish my explanation.
Recall bias would less likely be in play because we don't see evidence with nonperineal talc exposure. Recall bias are less likely to be in play because we only see it with epithelial ovarian cancer.
So, yes, cohort studies less, but there are other biases.
Q. Couldn't recall bias explain the difference between cohort studies and retrospective case-control studies?
MS. PARFITT: Objection. Form.
A. I don't think so. There's multiple other biases and multiple other strengths and limitations that would have to be considered.

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Q. You cite to Berge, a 2017 paper, in your report; is that right? Is that correct?
A. Yes.
MR. ZELLERS: Take a look at Exhibit 22.
(Article entitled "Genital use of talc and risk of ovarian cancer: A meta-analysis" marked Exhibit 22.)
MR. ZELLERS: Ms. Court Reporter, where do you want me to put it, maybe here, on top?
COURT REPORTER: Sure.
MR. TISI: Thank you.
BY MR. ZELLERS:
Q. Deposition Exhibit 22 is a paper that you cite by Berge, is the first named author, 2017. It's a recent meta-analysis; is that right?
A. Yes.
Q. Go to Page 6 of the Berge paper, Exhibit 22.
The authors conclude that, "Information bias from retrospective self-report of talc use is a possible explanation for the association detected in case-control studies." Is that right?
A. Yes.

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Q. What was your methodology for discounting the effect of recall bias in the population-based, case-control studies?
A. I mean, it's not like there's a -- once recall is operational, there are no methods that you can and do discount. But just the quality and, you know, the quantity of evidence over studies and the fact that even the cohort studies, despite these limitations, show an increased risk suggests that recall bias, while it is potential, cannot explain -- be the only explanation for a causal link between talc and ovarian cancer. You cannot adjust for recall bias after the completion of the study.
Q. What is the rate of error in that methodology?
A. I think that none of them have calculated it. And Dr. Cramer has done in his last study. And it appears that you'd have to need a significant degree of recall bias. And I am going to reference my report.
Q. Okay. Didn't the cohort studies involve a much greater --
A. I'm not done.
MS. PARFITT: Excuse me.

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A. I'm done.
MS. PARFITT: One moment. He wanted to reference something in his report.
A. Yeah. The risk of exposure would have to be very high to nullify the increased risk.
Q. Didn't the cohort studies involve a much greater number of women than the case-control studies?
MS. PARFITT: Objection. Misstates the evidence.
A. Yeah. But their combined number of ovarian cancer cases was 890. So power is only -- depends on the number of cases.
Q. What was your methodology for weighing the power of the cohort studies versus the case-control studies?
A. I mean, retrospective calculations of power are, you know, not really recommended once you already have the results. I mean, we already see that the overall cumulative evidence from many meta-analyses suggests an increased -- you know, provides an increased risk.
And we know that there's thousands of cases in the case control. There's, you know, I don't know how many cases in the cohort, so we know

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that the case-control stories are more powered.
Q. Do you agree that some case-control studies have shown statistically significant findings and others have not?
A. Yes.
Q. What is your methodology for weighing the lack of consistency in statistical significance across studies?
MS. PARFITT: Objection. Form.
A. I can answer that. Yeah.
So the methodology for correcting the lack of significance, that's why you do a meta-analysis. That's an inverse variance weighted meta-analysis. You -- so all of these studies have accounted for the fact that their confidence intervals are crossing 1. And that's how they have accounted for lack of a statistical significance.
So you can see that all of these estimates are weighted by sample size. So --
Q. Do you agree that if a study does not show a statistically significant association, it could mean that no risk exists? Correct?
MS. PARFITT: Objection. Form.
A. In the context of that study. But,

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again, I am looking at the cumulative evidence.
Q. It could mean -- strike that.
It could just be occurring by chance; is that right?
MS. PARFITT: Objection. Form.
A. I'm looking at the whole body of evidence.
In the context of a single study, yes.
Q. If a study is underpowered it could be because the difference in risk is too small to detect such as a risk ratio smaller than 1.15; isn't that right?
A. Yes. It's possible.
Q. All right. You have a criticism in your report of the Nurses' Health Study; is that right?
MS. PARFITT: Objection to form.
A. I don't have -- again, I don't have criticisms. I have pointed out the strengths and limitations.
Q. Well, let's look at some of those.
On Pages 40 and 41 of your report, you discuss the Gates 2008 study; is that right?
A. 40. Yes.
Q. The Gates 2008 study showed a

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statistically significant increased risk of total epithelial ovarian cancer; is that right?
A. Let me just look at it. There's so many of these. Yes.
Q. The Gates 2008 study used data collected in the Nurses' Health Study; is that right?
A. Yes. There was another part to it as well.
Q. In the Nurses' Health Study, the participants were asked about their talc exposure in one questionnaire in 1982; is that right?
A. Yes.
Q. When they were asked about their talc use, the participants were between 36 and 61 years of age; is that right?
A. Yes.
Q. As you state in your report, you agree that, although talc exposure -- and I'm looking at Page 41 --
A. Yes.
Q. The first paragraph. You agree that, "Although talc exposure was only measured in the 1982 Nurses' Health Study questionnaire, when participants were between 36 to 61 years of age,

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the number of users who began talc use after this is likely small, as shown by the fact that more than 95 percent of controls with regular talc in the NECC reported talc use before age 35."
A. Yes.
Q. Is that correct?
A. Yes.
Q. Later in your report, on Pages 47 and 48, you discuss the Gertig 2000 study; is that right?
A. Yes.
Q. That study also uses the data from the Nurses' Health Study; correct?
A. Yes. It's all part of the same cohort.
Q. That study, Gertig 2000, did not find a statistically significant relationship between daily talc use and all types of ovarian cancer; is that right?
A. Yeah. Again, I mean, they are different -- they're the same cohort with different follow-up time, different design. But it did not. And it found an increased risk for serous ovarian cancer.
Q. Gertig 2000, that study also relied on the national -- strike that -- the Nurses' Health

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Study questionnaire; correct?
A. Yes.
Q. And you cite that on Page 48 of your report, second paragraph; is that right?
A. Yes.
Q. You state, "Further, as discussed above, determining never use, based only on a one-time question, near the start of the study, 14 years prior to terminating the study in 1996, introduces undirectional behavioral change bias, likely misclassifying some ever users who used talc during the study as never users and biased the findings toward the null."
Is that what you state in your report?
A. Let me just read it. Yes.
Q. So when you discuss the Gertig 2000 study, you say that, because the participants in the Nurses' Health Study were only about or only asked about talc use once, near the beginning of the study, women who started using talc after they completed that questionnaire could have been misclassified as never users; is that right?
A. Yeah.
Q. But when you talk about the study that you believe supports your opinion --

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A. Yeah.
Q. -- Gates 2008, you recognize that the vast majority of women who use talc initiate use before age 36; is that right?
A. Yeah. But it does not -- both points are valid. I mean, I'm just stating the limitations of the Gates study and the Gates analysis. So.
I don't see an incongruity that you're trying to point out. I'm just saying the proportion of women who were never users, the number of users who began is likely small. But it still does not eliminate the possibility of unidirectional behavioral change bias.
Q. When you're looking at a cohort study, Gertig 2000 that does not support your opinion, you're talking about limitations; correct?
MS. PARFITT: Objection. Misstates his testimony.
A. I'm not talking about a study that does not support mine. I'm looking at the strengths and limitations of a study.
Q. You state two different things, depending upon whether you're talking about Gates 2008 or Gertig 2000; correct?

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MS. PARFITT: Objection. Misstates his testimony.
A. I am not.
First of all, they are two different analyses of a cohort. So they're not two different things about.
And I'm pointing out, you know, the reasons that that -- so I'm, you know, pointing out in Gates that, yes, talc exposure is a single-time exposure. And it is -- you know, introduces an element of bias.
But I'm also pointing out in Gates why that bias is likely to be, you know, small coming from the other consortium.
Q. But you don't say that when you discuss Gertig 2000, do you?
A. Yeah. Because it wasn't done in conjunction with the NECC consortium.
Q. All right. Look at Page 49 of your report. You discuss the Houghton 2014 study; is that right?
A. Yes.
Q. All right. Houghton did not find a statistically significant increase in the risk of ovarian cancer with perineal talc use; is that

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right?
A. Yes.
Q. Houghton did not find a statistically significant increase in the risk of ovarian cancer with use of talcum powder on sanitary napkins or diaphragms; is that right?
A. Yeah. They found an increased risk which was not statistically significant.
Q. And Houghton 2014 did not find a statistically significant increase in risk of ovarian cancer with increasing durations of use or when stratified by age or tubal ligation status; correct?
MS. PARFITT: Objection. Form.
A. I don't know that specific. I mean, you'd have to show me. Again, I don't remember these studies offhand.
Q. Like the Nurses' Health Study, the Houghton 2014 authors ask participants about their talcum powder use at the participants' entry into the study; is that right?
A. Yes. And they don't update during a follow-up, introducing, you know, bias.
Q. On Page 50 of your report, second paragraph, you note that the average age of the

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participants in the Houghton 2014 study was 63.3 years at baseline, with 12.4 years of follow-up on average; is that right?
A. Yes.
Q. And then you say that, because participants were not asked again about talcum powder use during follow-up, people who initiated talc use after the study began were being misclassified as never users. Is that right?
A. Yes.
Q. So, again, when the study supports your opinion, you recognize that the vast majority of perineal talc users begin that use well before age 63.
MS. PARFITT: Objection. Misstates testimony.
A. I don't recognize that. How do I recognize that? I'm just citing that, in Gates, they provided that opinion. Yeah.
In the Gates study, they quoted data from the NECC, that that's one study that provides. I don't know what's happening in the -- in this Houghton study, that vast majority. That's something that you are providing. And you provide data that the vast majority of users

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began --
Q. It's something you cited in your report; correct?
A. Yeah. But it doesn't mean that that applies to, you know, this Houghton study as well.
Q. And that's my point. You take a piece of information in terms of when women begin their talc use. You apply it differently in your analysis of studies that favor plaintiffs' position than studies that do not favor plaintiffs' position?
A. I'm sorry. I have to object.
MS. PARFITT: Objection.
A. I have to object. This is a mischaracterization of my testimony. I mean, I have to object to this. Because -- no, I have to.
MS. PARFITT: Let him finish. Let him --
A. Because you are mischaracterizing my testimony.
Yes, I point out the limitations in one section that, you know, a majority of women. And I also point out the unidirectional change bias,

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and both are entirely congruent with each other. But yes --
Q. Tell --
A. Yes.
Q. Are you finished?
A. Yes.
Q. All right. On what are you relying to opine that enough women begin talcum powder use in their 50s and 60s such that the results of Houghton or Gates 2000 are biased toward the null?
A. Well, I mean, we know -- exactly. I mean, we don't know that. I mean, we can't -- even a small amount, and that's important to know, that even a small amount of users was class- -- because we didn't ask those questions. So even a small amount of users who had moved to the other category would have nullified -- you know, would have biased it towards the null.
Q. Based on all your review, the data that you came across and that you cite in your report, are that the vast majority of women begin talc use in their 20s or earlier; correct?
A. No. I cite that in the NECC. That's the data I came across. And that's why it is

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cited. So to mischaracterize it as not being cited is incorrect.
Q. What is the latency period for ovarian cancer?
A. I don't know a specific number. It's, you know, several years.
Q. Several years.
That's your testimony based upon all of the data and material you've reviewed?
A. Yes. I mean --
MS. PARFITT: Objection.
Q. You've -- you've been referring to Penninkilampi; is that right?
A. I don't know the name. Yes.
Q. But let me give it to you and we can both see if we can pronounce it together.
MS. PARFITT: Before we start, it's about 12:20. We do have lunch coming. May I just take two minutes to see if it's here?
MR. ZELLERS: Sure. Or you can let me ask a couple of questions about this study and we can take a break, but whatever your preference is.
MS. PARFITT: What's your preference?
THE WITNESS: Let's do it.

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MR. ZELLERS: So I'll ask just a few questions about this study --
MS. PARFITT: And if it's not here --
MR. ZELLERS: -- then we'll take a break, because we've been going for a while.
(Article entitled "Perineal Talc Use and Ovarian Cancer, A Systematic Review and Meta-Analysis" marked Exhibit 23.)
BY MR. ZELLERS:
Q. Doctor --
A. I think we need a break in five minutes. I need a break. I don't know about you.
Q. We don't want to wear you out.
A. It's only half. Not even half the way.
Q. I'm handing you Exhibit 23. This is the Penninkilampi meta-analysis that you have referred to in your report and also in your testimony; is that right?
A. Yes.
Q. You rely on this meta-analysis, Deposition Exhibit 23, in forming your opinions; is that right?
A. As one of the studies. Yes.
Q. It's a 2018 meta-analysis; is that

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right?
A. Yes.
Q. Are you aware that this meta-analysis by Penninkilampi does not include the Gates 2010 update of the Nurses' Health Study?
A. When you say the Gates 2002 -- the study that we --
Q. What we looked at before was Gates 2008. And we also looked at Gertig 2000 --
A. All these different studies.
Q. That's all right.
You're aware that there are several different cohort studies relating to the Nurses' Health Study; is that right?
A. Yes.
Q. What we talked about earlier was the Gertig 2000 study.
A. Okay.
Q. Correct?
A. Yes. And before that, we talked about --
Q. The Gates 2008.
A. Okay.
Q. Are you aware that Gates, in 2010, updated the Nurses' Health Study, which we have

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referred to as Gertig 2000?
A. Yeah. I have. It's cited in my report as well, 92.
Q. Are you aware that Penninkilampi does not include the Gates 2010 update of the Nurses' Health Study?
MS. PARFITT: Refer to your --
A. Can I take a look?
MS. PARFITT: Of course, you can.
Q. Sure.
A. Yeah. It cites Gertig.
Q. But it does not cite Gates 2010; is that right?
A. I don't see it.
Q. Do you weigh this study, the meta-analysis by Penninkilampi, less because it does not include the Gates 2010 study?
A. I mean, all of these meta-analyses, most of them have found, you know, similar odds ratio. You know, some of them have made different decisions.
They have made -- for example, they made decisions about more than 50 cases. Other -- if you look at the Taher meta-analysis, they decided, based on -- that a New Castle Tawas

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Skill Rating will include studies.
So you have to review that. Just because they excluded Gates 2010, I wouldn't weigh it differently. That's my answer.
Q. Gates 2010 tends to negate an association between perineal talc use and ovarian cancer; correct?
MS. PARFITT: Objection. Misstates the evidence.
A. So negates the evidence? I mean, in fact, if you look at influence analyses conducted by Taher, it sort of doesn't matter which study you take out and which study you take in. All of the estimates are statistically significant.
Q. If you're going to do a reliable meta-analysis, you should include the pertinent studies; correct?
MS. PARFITT: Objection. Misstates his testimony.
A. Just give me a second.
Yeah. I mean, you have to include the permanent study -- but as we know, as we know, people have made different decisions, like Taher made separate decisions, Berge has made separate -- the previous analysis made.

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So I think it's quite reliable and, you know, they were justified. They said we're going to look at case control with more than 50 cases. So I don't consider it unreliable for that reason.
MR. ZELLERS: Let's take a break.
THE VIDEOGRAPHER: Here ends Media No. 2. Off the record, 12:24 p.m.
(Lunch recess was taken.)
THE VIDEOGRAPHER: Here begins media No. 3 in today's deposition of Sonal Singh, MD, M.P.H. Back on the record, 1:02 p.m.
BY MR. ZELLERS:
Q. Dr. Singh, another Bradford Hill overview factor that you considered is dose-response; is that right?
A. Yes.
Q. Which studies show a dose-response?
A. Let me just refer to my report.
So in -- you know, in assessing dose-response, it's very challenging with an exposure such as perineal talc, particularly because, you know, you need to know the amount, you need to know the duration, you need to know the intensity of exposure. So there are

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challenges.
The second is the challenge of modeling dose-response. When we say dose-response -- or exposure outcome, is it linear monotonic relationships?
And, you know, several studies, some measure duration, some measure intensity, some measure duration and frequency. So as I cite in my dose-response section, which I'm trying to find -- I'm sorry -- yeah, Page 56 of my report.
Q. Which studies show a dose-response?
A. I mean, this is, you know, references -- with increased frequency, 51 to 55. Duration, 52 to 54. Frequency and duration, 58 -- 48 to 54.
Q. Doctor, which studies did you review that show a dose-response?
A. These are the studies that I cited.
Q. What page are you looking at?
A. Page 56.
Q. Are there studies that do not show a dose-response?
A. Yes.
Q. Do you cite those studies that do not show a dose-response in your report?

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A. Yes, I do.
Q. On what page?
A. Just give me a second. I know I have cited them, and I'm just trying to find where.
Yeah. None of the cohort studies were able to conduct meaningful dose-response because they did not collect durational.
Q. Are those the only studies, the cohort studies that did not find a meaningful dose-response?
A. No. There were several --
MS. PARFITT: Objection to form.
A. There were other case-control studies. No. If you take out 41, 55 -- I mean, these references cite above -- that are, you know, included in the sections, and I talk about their dose-response in the respective section.
Q. What is your justification for disregarding the studies that did not show a dose-response?
MS. PARFITT: Objection. Form.
A. So I did not disregard these studies. They are included in the report. So, obviously, the cohort studies already are, and we can go through the case-control studies, which did not

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show dose-response and are included.
Q. One of the studies you reviewed and considered and relied upon was the Cramer 2016 study; is that right?
A. Yeah.
(Article entitled "The Association Between Talc Use and Ovarian Cancer, A Retrospective Case-Control Study in Two US States" marked Exhibit 24.)
BY MR. ZELLERS:
Q. Exhibit 24 is the Cramer 2016 study; correct?
A. Yes.
Q. This is a retrospective case-control study published in 2016; is that right?
A. Yes.
Q. You claim in your report that this study shows a trend for increasing risk by talc years on Page 46, the last paragraph; is that right?
A. Yes.
Q. Let's take a look at whatever the study shows. Turn to Page 337 of Exhibit 24, the Cramer 2016 study.
A. 337? Yes.

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Q. On 337, there's a table that shows the risk of ovarian cancer for women who used talc daily for one year, one to five years, five to 20 years, and more than 20 years. Is that right?
A. Yes.
Q. There was only statistical significance for the time periods of one to five years of use and more than 20 years of use; correct?
A. Yes.
Q. If there is a dose-response, shouldn't there continue to be statistical significance with increased exposure?
MS. PARFITT: Objection. Form.
A. Yeah. So that is -- I'm just concluding what they concluded. The trend for frequency of use was significant, but the trend for use -- years use was flat. And if you look at Page 337, the last line of that paragraph, "Even with this imprecision, the trend remained, although the increase was less monotonic."
Q. When we look at the data, there is only a dose-response -- strike that.
The data only shows statistical significance for one to five years of use. It does not show statistical significance for one year or five to

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20 years; correct?
MS. PARFITT: Objection. Misstates the evidence.
A. Yeah. So let's go to --
Q. Is that correct?
MS. PARFITT: Objection.
A. Yes. But let's go to the section of my testimony in which -- report which discusses how dose-response analysis should be interpreted, because they lose statistical power. So subgroup tests lose statistical significance, and I'll point out --
Q. You --
MS. PARFITT: Excuse me. I think he's still --
A. Yeah. I'm trying to explain something. Yeah. We are talking on the subject of dose-response. And one must be careful in interpreting data from the subgroup analysis such as analysis of dose categories or, you know, as subgroups. The results are important. If the test is not significant, there's lack of significant difference. However, such subgroup tests can be underpowered because of reduction in sample size.

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Q. Doctor, if there is a dose-response in a study such as the Cramer 2016 paper, looking at the data, shouldn't there continue to be statistical significance with increased exposure?
MS. PARFITT: Objection.
A. No, no, you don't -- it doesn't have to be statistical significance with, you know, increased exposure. I mean, you look at the test score interaction.
So I don't think that, with each category of exposure, you're already -- you have a power for a study. Now with each, you're decreasing the number of users, so you're not going to get statistical significance.
Q. Then why do you get statistical significance at greater than 20 years of daily use?
A. Yeah. Because there's differential, you know -- at that point, you know, there's more -- there's, you know, more case subjects have ovarian cancer.
Q. Why do you not have statistical significance at five to 20 years?
A. Because it's underpowered at that time.
Q. Why do you not have statistical

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significance at one year?
A. It's underpowered.
Q. But it is appropriately powered at one to five years?
A. Yes. Based on the number of cases.
Q. Isn't this an instance where you're cherry-picking the data that is favorable to plaintiffs' position and ignoring all of the data which would tend to refute plaintiffs' position?
MS. PARFITT: Objection. Form.
A. I don't know what the plaintiffs' position -- but what I'm trying to say is this is -- my interpretation of dose-response is based on, you know, not based on statistical significance. So that's all.
Q. Which studies show a dose-response for asbestos exposure and ovarian cancer?
A. I have not evaluated the causal link between asbestos and ovarian cancer. Other agencies have, and they have opined that it causes ovarian cancer. But I have not.
Q. Do you have any idea how much talcum powder reaches a woman's ovaries each time she uses it?
A. I have not conducted that -- conducted

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that testing to determine how much talcum powder reaches a woman's ovary after each application.
Q. Do you have any idea how much asbestos reaches a woman's ovaries each time she uses talc, assuming that talc powder is contaminated with asbestos?
MS. PARFITT: Objection. Form.
A. I have not conducted that assessment.
Q. How much heavy metal exposure reaches a woman's ovaries, assuming that there are heavy metals in talcum powder?
MS. PARFITT: Objection. Form.
A. I have not conducted that assessment.
Q. Do you know that heavy metals, chromium, cobalt and nickel, are in vitamins?
A. Yeah. They are in, you know -- they are ubiquitous in various other areas as well.
Q. They're in food; right?
A. I don't know which one is in which. Yeah. I can't be specific.
Q. In drinking water?
A. I don't know. I don't want to say yes to whichever.
Q. It's in bottled water?
A. I don't know that.

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Q. Are heavy metals, chromium, cobalt and nickel, considered essential nutrients in the body?
MS. PARFITT: Objection.
A. Yeah. I mean, that's, you know, it's -- pertaining to this case, the question is not that, whether they are in drinking water.
I asked myself this question, causal question, what constitutes talcum powder products. And to that effect, if there are substances such as, you know, chromium, cobalt, and other heavy metals that have been, you know, classified as Grade I or Grade II carcinogens that provide further evidence of a causal link, whether they are present in air, ambient air, that's not the assessment I've done, and I'm not making a causal claim that chromium, per se, is causing that ovarian cancer in that causal framework.
Q. You have no evidence whatsoever that the blood or tissue levels of any trace heavy metals are higher in genital talc users compared to nonusers; correct?
MS. PARFITT: Objection. Form.
A. Blood or genital talc. I'm sorry. Can

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you repeat?
Q. Sure. I'll ask it again.
You have no evidence that the blood or tissue levels of any trace heavy metals are higher in genital talc users compared to nonusers; correct?
MS. PARFITT: Objection. Form.
A. Yeah. But I do know that there is perineal talc application, and at least from the documents I have reviewed, that, you know, asbestos is present in talc, at least from the documents I've reviewed, from the studies that I've reviewed, and from a -- as you say, the excerpts of the deposition.
And, you know, whether these are in blood levels or, as you said, in the uterine tissue, no, I don't know that.
Q. Another Bradford Hill overview factor is biological plausibility; right?
A. Well, it's actually plausibility.
Q. Plausibility means that a biological mechanism exists; correct?
A. Well, that's what we mean. But if you actually go back and read Bradford Hill, he was talking even about social factors. Yes, but, you

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know, we've gone forward and interpreted that as biologic plausibility.
Q. The biological mechanisms of cancer are not your area of expertise; is that right?
MS. PARFITT: Objection.
A. Yes. But, again, the question for me was not, you know, to elucidate every precise step either in the occurrence of ovarian cancer or the talc installation into the development.
The precise question was, you know, the epidemiology shows these findings. Whatever is the data in biology, does it support or does it refute, you know, these findings in epidemiology?
Q. On that topic, biologic plausibility, you defer to other experts; is that right?
MS. PARFITT: Objection.
A. Yeah. I would defer to other people for more details on, you know, precise mechanisms of ovarian cancer.
But I do have -- and I'm an epidemiologist. I mean, I can't -- so that's why I just can't look at whether it's Cramer or Penninkilampi or Berge in isolation. We have to look at the whole evidence, including epidemiology, including -- but, yes, I can -- I have that experience to

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infer from whatever the biological evidence that I've reviewed, that there's, you know, evidence that supports biologic probability. There are some studies that, you know, don't support that claim.
Q. My question simply was if you defer to other experts on the topic of biologic plausibility.
MS. PARFITT: Objection.
Q. You do; correct?
MS. PARFITT: Objection. That's not his testimony.
A. I won't just defer to them. I'm just providing my own opinion. Yeah. I mean, they can provide -- you know, it depends. If it's a plaintiff expert, a defense expert. I mean, how do I know? I can't defer to somebody without reading their opinion; right?
Q. Is all ovarian cancer caused by the same mechanism?
A. No. And neither is any kind of cancer.
Q. Different subtypes of cancer have different biological mechanisms; correct?
A. Yes. But we are dealing with biologic plausibility.

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Again, I don't need to know the precise biological mechanisms to arrive at a causal opinion.
Q. If talc is associated with all subtypes of epithelial ovarian cancer, or with different subtypes in different studies, doesn't that suggest that the association is by chance?
MS. PARFITT: Objection. Misstates the evidence.
A. I mean, again, I don't know enough details about the biologic plausibility of each ovarian cancer subtype to say that, you know, talc would be, by chance, alone. I'd defer to, you know, people who evaluate these.
Q. There is no one biological mechanism that could tie all of these subtypes together, is there?
A. I will defer to people with more experience. I don't know that. What I know is biological plausibility mechanisms that inform the hypothesis that I was looking at.
Q. How does talc reach the ovaries?
A. Well, you know, talc migrates from, you know -- my understanding and opinion is that, you know, perineal application of talc, you know,

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migrates upwards and upwards through the, you know, vaginal canal and migrates to.
Q. Is that an area of your expertise?
A. Again, no. But I have reviewed the studies, several studies that -- some studies that I cite, several studies that were added. And it's quite well accepted, at least in the gynecological community, that there's, you know, particulate matter can migrate upwards.
Q. What studies support the theory that talcum powder applied externally migrates from the perineal region to the ovaries?
A. Again, I reviewed various studies on migration.
Q. Can you name them for me?
A. I'm going to look at it.
Yeah. So I cite several studies in this section on migration. And, again, this in the context of biologic plausibility. Is it plausible that particulate matter, such as talc, can migrate? And, again --
Q. What page are you looking at?
A. Sorry. 57.
Q. What studies are you relying on?
A. Yeah. So I'm relying on the studies

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described by, you know, Heller, 64.
Q. Any others?
A. 65.
Q. What is 65?
A. I'll have to go take a look.
It's Henderson, I think, but I don't want to -- these are big documents. Yeah, it is Henderson.
And then 66 is presence of talc in lymph nodes and then --
Q. Who is the author?
A. Cramer.
And then supportive evidence of migration of other, you know, particulate matter comes from, you know, 68, 87 and --
Q. 68 is what?
A. 68 is Justin.
Q. Eighty -- is it -- 87 is what?
A. Ness.
Q. Is who?
A. Ness. Ness 2000.
Q. Cramer is a litigation consultant and expert for plaintiffs in the talc litigation; is that right?
MS. PARFITT: Objection.

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A. Yeah. I know that.
Q. Ness is an expert for plaintiffs in the talc litigation; is that right?
MS. PARFITT: Objection.
A. I'm not aware of that.
Q. So Justin, that dealt with glove powder; is that right?
A. Which one was that, 68?
Q. 68.
A. Yes.
Q. Isn't it true that that study did not involve perineal use, but an exam with force to the cervix?
A. Yeah. You know, and I'm relying on it, again, for biologic plausibility. It does not involve talc. So, you know, it's glove powder in --
Q. Isn't it true that they found some particles in women who were examined with powder-free gloves?
A. Yes.
Q. Heller, didn't Heller find talc in tissues in all 24 patients, including the 12 who did not use perineal talc?
A. Yes.

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Q. What is the evidence in the ovarian tissues that have been studied of granulomatous reaction which is what you would see if there was a huge amount of talc?
A. Well, I mean, I'm not opining that there is a huge amount of talc, but others have found talc in the ovaries. I am just -- my opinion is that it is biologically plausible. I mean, you know, the FDA has stated that it is biologically plausible for particles, retrograde particles to migrate.
And so I'm opining on that. I'm not saying that talc is in the ovaries and it's inducing this granulomatous reaction. I mean, these people have found that it can occur.
And this is sufficient evidence for my opinion to support on biologic plausibility.
Other studies, which I cite in my report, which, you know, for example, monkey models, couldn't, you know detect -- didn't detect translocation. So there are studies that don't.
Q. Can you cite any article that shows granulomas, fibrosis, or adhesions anywhere up the reproductive tract of a woman as a result of her external genital talc application?

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MS. PARFITT: Objection. Form.
A. I did not review those studies, if there are.
Q. In your report, you say that, "The migration theory is supported by findings of a deceased risk" -- strike that.
In your report, you say that, "The migration theory is supported by findings of a decreased risk of ovarian cancer with tubal ligation and hysterectomy." Pages 18 and 19.
Is that right?
A. Yes.
Q. Don't the studies pertaining to tubal ligation show mixed results?
A. No.
MS. PARFITT: Objection.
A. As far as --
MS. PARFITT: Sorry.
A. I mean, as far as I'm aware, you know, tubal ligation and hysterectomy are protective risk factors for ovarian cancer.
Q. That's your opinion based upon your review and analysis of the literature; is that right?
A. Yeah.

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Q. Take a look at the Cramer article that we referred to before, Exhibit 24. This is Cramer 2016.
Do you have that in front of you?
A. Oh, my copy?
Q. Yes. You have a copy.
A. Yes. Which page?
Q. Take a look -- well, Cramer found a significantly greater association between talcum powder use and ovarian cancer for women who had a tubal ligation or hysterectomy. Isn't that true?
A. Where is that?
Q. Look at the bottom of Page 337 of Exhibit 24 to the top of page -- look at 337.
A. And which table?
Q. I'm sorry. Look at the bottom of Page 337, that carries over to the top of Page 339. This is Cramer describing his results; is that right?
A. Yes.
Q. Tell me if I'm reading this correctly, and I'm starting at the bottom of Page 337.
"By test for interaction, Column 3, the association was significantly greater for women who were African American, had no personal

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history of breast cancer, had a tubal ligation or hysterectomy, were pre-menopausal or were post-menopausal and used HT."
Is that correct?
A. Yeah.
Q. So, in fact, Cramer did find a significantly greater association between talcum powder use and ovarian cancer for women who had a tubal ligation; is that right?
A. Yeah. But my -- my point, in Page 57, is that, you know, first of all, that's more than just one Cramer. There are several studies that -- in inferring biologic plausibility, tubal ligation and hysterectomy are protective of ovarian cancer. It is not that talc in this had a higher risk among those.
I mean, those, again, those are not two incongruent arguments. I mean, Cramer is making a separate argument that, in his study, he found a higher risk among those who had tubal ligation or hysterectomy.
Q. If you're correct in the opinion that you set forth in your report, you would have expected the Cramer study to show a decreased risk of ovarian cancer for women who had tubal

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ligation or hysterectomy; correct?
MS. PARFITT: Objection. Form. Misstates his testimony.
A. Yeah. I mean, I don't -- I mean, that's probably, in that study. Yeah.
Q. How do you account for the fact that Cramer and the authors of this 2016 paper found a significantly greater association among women who had a tubal ligation or hysterectomy?
A. I have no -- you know, you can find different studies have different findings, but, overall, we know that tubal ligation and hysterectomy are protective.
Q. The Gertig 2000 Nurses' Health Study, that's also a study that you have reviewed; is that right?
A. Yes.
Q. That study did not show a reduction of ovarian cancer in talc users who have had a tubal ligation; correct?
A. Which page is that?
Q. I'm just asking, based upon your review of that study.
A. I can't answer. You know, there are so many different -- can I ask for the Taher

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appendix, because that actually breaks it down by tubal ligation and hysterectomy.
You're asking very specific questions. I need to have specific materials.
MR. TISI: I have them.
Q. What are you asking for?
A. You asked a question about tubal ligation.
Q. I understand. What are you asking counsel for plaintiffs to get you?
A. The Taher appendix.
Q. You want to go back and look at the Taher --
A. Appendix. Because they did stratify the analysis by hysterectomy and tubal ligation.
Q. That's the 2018, unpublished paper; is that right?
A. Yes.
Q. All right. Did the Houghton -- as they're looking for this --
A. Yeah. Sure.
Q. Did the Houghton two thousand -- strike that.
The Houghton 2014 study also did not show a reduction of ovarian cancer in talc users who

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have had tubal ligation; correct?
A. Again, you know, I don't want to agree or disagree with you without just looking at it. I don't think I comment on it.
Q. Would you agree or can you agree that both Gertig 2000 and Houghton 2014 were large prospective cohort studies; right?
A. Yeah. But we've already discussed their limitation in terms of they were not designed to study the talc ovarian cancer. They had prevalent user biases. You know, they lost a lot of users and cases of ovarian cancer. You know, they had misclassification.
And, yes, they were large studies, but had small number of ovarian cancer cases.
MR. KLATT: Objection. Nonresponsive.
MR. ZELLERS: Join.
Q. You read the Ter Riet 2013 meta-analysis; is that right?
A. Yes.
Q. You rely on that; correct?
A. Yes.
MS. PARFITT: Objection.
Q. The Ter Riet 2013 meta-analysis also did not show a reduction of ovarian cancer in

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talc users who had a tubal ligation; correct?
A. I mean, I think I need to look at the data. I think -- I don't have it. We are trying to get it, so we'll have to wait.
I mean, you're asking me questions. I mean, you have to show me documents. I mean --
Q. Well, you made a statement in your report --
A. How can I make a statement in the report around Taher, because it wasn't even available at that time?
Q. What I'm trying to do is ask you --
A. Sure.
Q. -- about the statement in your report, where you say that, "Migration theory is supported by findings of a decreased risk of ovarian cancer with tubal ligation and hysterectomy."
A. And I'm just stating that I just need to look at a figure in the Taher appendix and then I'll be able to answer that. That's all.
Q. Well, we saw that Cramer doesn't show that; right?
A. Yes.
Q. You're not aware that Gertig 2000 or

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Houghton 2014 shows that. Are you?
MS. PARFITT: Objection. Misstates his testimony.
A. You have not shown me that. You have not shown me documents to say one way or the other.
Q. When you did your analysis, didn't you look at the studies to try to see if they supported or refuted the points you were making?
A. I -- you know, I did not look at every subanalysis by, you know -- by whether it's, you know, pre-menopausal, post-menopausal.
Q. You cite Cramer 2016 as supportive of your position and opinions.
A. Sure.
Q. Is that right?
A. Well, again --
MS. PARFITT: Objection. Mis --
A. I don't.
MS. PARFITT: Let me get my objection in.
THE WITNESS: Sorry. Go ahead.
MS. PARFITT: No. My objection is in, I think.
Q. But then you ignore those portions or

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parts of Cramer 2016, Gertig 2000, Houghton 2014, Ter Riet 2013, Rosenblatt 2011, Wong 1999, Cook 1997, Harlow 1992, that don't support your position.

MS. PARFITT: Counsel completely misstates his opinion. The question misstates --

A. I don't even know what was the question, and I can't answer that because I don't know what the question was.

Q. The question is: When you opined in your report that the migration theory is supported by findings of a decreased risk of ovarian cancer with tubal ligation and hysterectomy, did you pick out just a couple of cases to look at and cite or did you try to see if there was consistency to that finding across all of the studies?

A. Yeah. So when I cite that, and you can see the citation, I am trying to make an inference about separate from talc use, and ovarian cancer, you know, is hysterectomy and tubal ligation protective of that.

So that's the inference. It's not that each of these studies, I'm trying to ignore, you know, the studies that you mentioned. I'm just trying

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to say, as you're looking at mechanisms, what would happen with tubal -- I'm trying to do the best to explain, tubal ligation and ovarian cancer.

If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and hysterectomy being, you know, protective.

Q. Do you agree with me, to have a scientifically valid opinion --

A. Sure.

Q. -- you need to look at all of or at least the important studies; correct?

A. Yeah. I did look at these studies.

Q. And, in fact, a number of the studies that you cite in your report --

A. Sure.

Q. -- don't support your position; correct?

MS. PARFITT: Objection. Form.

Support his position on tubal ligation?

Q. Well, right now, we're talking about migration, that the migration theory is supported

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by findings of a decreased risk of ovarian cancer with tubal ligation and hysterectomy.

A. Yeah. But it doesn't talk about, you know -- so if you look at the reference, in case-control studies and meta-analysis, let's look at the references. You know, so, yes, there's one. And if -- let's look at --

Q. Okay. Can you cite one reference?

A. Yeah. Let's look at that.

Q. All right.

A. Then let's look at 115. So when I cite 115, that's not even about talc. That's about tubal ligation and hysterectomy, in general, is it -- you know, so taking talc out of the equation, I'm trying to opine or understand whether tubal ligation and hysterectomy are protective factors, and then I can infer on talc, yes, should only Ness have been cited? Yes, there are other studies otherwise.

Q. And there are other studies, many studies --

A. Yes.

Q. -- that do not support your position; is that right?

MS. PARFITT: Objection. Form. His

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position on tubal ligation?

MR. ZELLERS: Yes.

MS. PARFITT: Thank you.

A. Yeah. So it's -- it's -- I think there's -- I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.

BY MR. ZELLERS:

Q. You should at least cite to or make some reference --

A. Yeah.

Q. -- right, to the studies that do not support that position?

A. Yeah. And I think that I have made it in the individual sections, and I can try to look for it, but it will take us time there.

Q. Isn't there evidence that if tubal ligation has a protective effect, the protective effect in ovarian cancer stems from the fact that the ligation procedure itself changes the fallopian tube cells?

A. I am not an expert --

MS. PARFITT: Objection.

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A. -- in, you know, this area to provide, you know, why it would do that.
Q. Did you review or are you familiar with Tiourin, T-I-O-U-R-I-N, a 2015 study?
A. Did I cite that? I don't remember.
Q. Are you -- is that study familiar to you?
A. I just can't remember the names. There are so many studies. If you show it to me, I can --
Q. I'll show it to you. You can tell me if it's familiar to you. And if it's not, I'll move on.
(Article entitled "Tubal Ligation Induces Quiescence in the Epithelia of the Fallopian Tube Fimbria" marked Exhibit 25.)
MR. ZELLERS: 25 is the --
A. No, it's not. I don't know about.
BY MR. ZELLERS:
Q. For the record, 25 is a 2015 study by Tiourin, T-I-O-U-R-I-N.
That's not a study that you reviewed or considered; is that right?
A. You know, I have to go through all the

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references, but I can't recall straight off whether it does.
Q. If talcum powder migrates from the perineal region to the ovaries, shouldn't exposure to talc be far greater in concentration in the rectal, vulvar, vaginal, cervical and uterine tissues?
MS. PARFITT: Objection to form.
Q. Because those are closer to the area of initial exposure?
MS. PARFITT: Same objection.
A. Yes. So, again, my -- I did not examine, you know, which areas of -- now, as an epidemiologist, I examine general exposures to, you know, products and their associations. Whether, you know, we want to know, yes, route of exposure, whether it's perineal application.
But, you know, the evidence that I examined was, you know, I did not distinguish within whether it was perineal or vaginal, vulvar. That would have been different.
Q. Let's go step by step.
You do agree that if talcum powder migrates from the perineal region to the ovaries, the exposure to talc would be far greater in

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concentration in the rectal, vulvar, vaginal, cervical, and uterine tissues which are closer to the area of the initial exposure; correct?
MS. PARFITT: Objection. Misstates his testimony.
A. I just don't have an opinion in terms of where it will be high or low. Because that's not my area of expertise.
Q. Talc particles should be causing inflammation in all those organs and areas; correct?
MS. PARFITT: Objection.
A. Again, that's -- that's, you know, I'm opining on biological plausible mechanisms of talc-induced ovarian cancer. I didn't look at, you know, whether it's vaginitis or vulvar or whether it's, you know, rectal inflammation. And that's not my area of expertise again.
Q. In fact, there are no studies that show inflammation as a result of genital talc use in any of those areas; correct?
MS. PARFITT: Objection. Misstates the evidence.
A. Again, I have not -- you know, my testimony and report on talcum powder products

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and inflammation is looking at, are there biological plausible mechanisms.
And, again, if there's no studies that provide that talc, in and of itself, causes inflammation, then there are no studies. But, you know, but there's still biologic plausibility.
MR. KLATT: Objection. Unresponsive.
Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical, or uterine cancer?
MS. PARFITT: Asked and answered. Objection.
A. I'm not aware of those. I have not reviewed those studies.
Q. As part of your report, you discuss a study published by Huncharik and others in 2007; is that right?
A. Yes. Let's bring it out, I mean, if you want to talk about that.
Q. I believe it's on Page 26 of your report.
A. Sure.
Q. Huncharik 2007 is a meta-analysis of

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studies on the relationship between ovarian cancer and using diaphragms that are dusted with talcum powder; is that right?

A. Yes.

Q. A diaphragm is inserted directly onto a woman's cervix; is that right?

A. Yes.

Q. On Page 26 of your report, you say that, "This meta-analysis is flawed because it only focuses on powder-dusted diaphragms"; correct?

A. Well, no. That's not the only flaw. I mean, there are several other flaws, including exclusion of loss category, data extraction analysis, which is, you know, really inclusion of inability studies that did not disaggregate.

I mean, the question is if you're asking about perineal exposure, yes, perineal -- diaphragms is one route of exposure. But that's not the only route of exposure that you should be concerned about.

Q. Do you state in your report, "The most important limitation with the Huncharik 2007 meta-analysis was its exclusive focus on talc powder-dusted diaphragms as the route of

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exposure, which could not inherently address the causal question of whether genital talcum powder dusting is associated with increased risk of ovarian cancer"?

Is that what you said?

MS. PARFITT: Counsel, do you have a copy of the -- otherwise, may I show him the Huncharik study so he's got it in front of him?

MR. ZELLERS: I'm just asking general questions right now. That was just a question, does he say that in his report. If he needs to review the study, then he can look at the study.

MS. PARFITT: I would appreciate that.

MR. ZELLERS: Sure.

MS. PARFITT: I just didn't want to pass something to him without your permission.

A. Yeah. I do state that.

Q. You say that, "Studies on the use of talcum powder-dusted diaphragms cannot address the question of whether perineal use is associated with an increased risk of ovarian cancer"; correct?

A. Where is that?

Q. It's what we just read.

A. No. It doesn't mean that. It just

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means that you cannot exclusively focus on one route of exposure. So it does not mean that it cannot in and of itself. You have to look at perineal-dusted diaphragm. You have to look at, other, you know, perineal applications.

Q. So putting aside inhalation for the moment, your opinion is that talcum powder travels from the perineal region to the ovaries through the woman's reproductive tract; is that right?

A. I mean, I don't even know through the ovaries. I know it migrates upwards. That's, you know, my opinion.

Q. So talcum powder must travel past the labia, through the vagina, through the cervix, and then to the uterus; is that right?

A. Yes. It migrates upwards through the vagina, you know, the tract.

Q. And then the powder travels through the uterus and into the fallopian tubes to reach the ovaries; is that right?

A. Well, I mean, I'm not -- again, I don't intend to elucidate, you know, the precise link that a study has shown that talcum powder -- I think we answered this earlier, I answered this

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earlier -- that I am not aware of one study that shows that. But, you know, several shows that talc ends up in the ovaries.

Q. Well, given how talc, talcum powder must travel to reach the ovaries, how can you exclude data about the relationship between ovarian cancer and talcum powder that is applied directly to the cervix?

MS. PARFITT: Objection. Misstates his testimony.

A. Nobody is excluding data. So this is not exclusion of this data.

But I am saying that this particular question of talc-dusted diaphragms, A, is an exclusive focus on one route of exposure, so it does not answer the causal question about perineal exposure.

And, two, it is not excluded. It's included and discussed and several flaws are noted, including, you know, data extraction errors for the most part, inclusion of studies.

And so -- and as can you see in my methodological rating of meta-analyses, it is weighted differently than others. So it is not excluded.

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Q. But you state, as the most important limitation of the Huncharik 2007 study, is the exclusive focus on talc powder-dusted diaphragms.
A. Yeah.
Q. And those diaphragms are applied directly to the cervix; is that right?
A. Yeah. Because -- because of its exclusive focus. If the study had, you know, other routes of exposure, yeah.
What I'm trying to say is its exclusive focus on one route of exposure cannot -- if you're just asking the question about dust, dusted diaphragm, then don't make inferences about perineal routes of exposure. You have to look at broader exposures.
Q. On what studies are you relying to say that talcum powder affects the body differently when it is applied to the perineal region and travels to the cervix compared to when it is applied directly to the cervix?
A. I have not made a distinction between those studies.
Q. And, in fact, when applied to the perineal region, the talcum powder would also be in close contact with a woman's urethra; is that

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right?
MS. PARFITT: Objection. Form.
A. Yeah. I mean, anatomically.
Q. Substances are capable of traveling up the urethra; correct?
A. I mean, yes. Just as we agree that, you know, talc can migrate upwards, substances can migrate through the urethra. If you agree talc can migrate upwards, then, you know, substances can migrate through the urethra.
Q. Women get urinary tract infections when bacteria travels up the urethra; correct?
A. Yeah.
Q. But studies do not show an increase in bladder cancer with talcum powder use, do they?
MS. PARFITT: Objection to form.
A. I did not ask the causal question about that. And, you know, I have not evaluated. Maybe there are studies that show decreased risk for all that I know. I just can't answer that question.
Q. And studies do not show an increase in rectal cancer with talcum powder use; is that right?
A. I don't answer the questions that I

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don't know anything about. I don't -- you know, I haven't reviewed it to answer that question.
Q. Do you have an opinion on whether inhaled talc can migrate to the ovaries?
A. Yeah. I mean, I think the primary route of exposure is, you know, reproductive, but there are some potential, I would say, you know, potential plausible mechanisms that, you know, when perineal application is applied, it can get inhaled through the lungs and potentially reach the ovaries. But I think that that mechanism is probably not as plausible as the reproductive mechanism.
Q. Well, in fact, studies of talcum powder use failed to show a statistically significant association between nongenital use of talcum powder and ovarian cancer; correct?
MS. PARFITT: Objection. Form.
A. Yeah. And I've cited those studies.
Q. If inhaled talc could migrate to the ovaries, wouldn't you expect to see increased ovarian cancer risk with nongenital use of talcum powder?
MS. PARFITT: Objection.
A. Well, I mean, it also depends on, you

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know, the quantity of inhalation, the degree of talc that's -- and I don't know enough about that to say that, yes, there's a sufficient quantity, you know, migration to cause that. I don't know which studies have evaluated sort of inhaled talc and ovarian cancer.
Q. Well, let's look back at Cramer 2016, Page -- or Exhibit 24. Do you have that in front of you?
A. Yeah.
Q. In that study, Cramer found no apparent risk associated with nongenital talc use; isn't that correct?
A. Yeah. And I think I cite that in my report, too.
Q. You don't disagree that Cramer, in his study, 2016, did find no apparent risk associated with nongenital talc use; correct?
A. Yeah.
Q. The same result was found in the pooled analysis that was done by OCAC, Ovarian Cancer Association Consortium; is that right?
MS. PARFITT: Objection. Which study are you referring to? What year? There have been many studies by OCAC.

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MR. ZELLERS: I'm referring to Page 341 of the Cramer article. Page -- strike that.

The second and third paragraphs.

BY MR. ZELLERS:

Q. Tell me when you have that, Doctor.

A. 341. Discussion?

Q. Yes. So in the second and third paragraph, I'm reading the second sentence. "Talc use regularly" -- strike that.

"Talc used regularly in the genital area was associated with a 33 percent increase in ovarian cancer risk overall while no apparent risk was associated with talc used only in nongenital areas."

A. Yeah. And I agree with their opinion.

Q. All right. Do you also agree with the next sentence? "Our results are consistent with the recent pooled analysis from the OCAC which reported that use of powder on genitals is associated with a 24 percent increased risk and no effect of nongenital use of talc."

A. Yeah.

Q. Have you ever performed any study yourself pertaining to whether inhaled talc can migrate to the ovaries?

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A. No. And I would have a different job. That's not my area of expertise.

Q. And you can't, as we sit here, cite me to such a study; correct?

A. Well, I don't know if it's -- I'll go back to my report and just cite that -- that Dr. Luongo, you know, has done analyses which say that inhaled talc can migrate.

Q. You're not expressing that opinion here today; correct?

A. No. I'm not. I'm not vouching for his testimony.

Q. Assuming baby powder can reach the ovaries, what is the method by which baby powder causes ovarian cancer?

A. So, yeah. I mean, we talked about, you know, potential biological mechanisms of inflammation.

And, again, I don't -- in my inference on biologic plausibility, I don't intend to offer the opinion that, A, I know the precise biological mechanisms which cause biological -- ovarian cancer or the precise steps by which talc causes it.

But, you know, there are several, you know,

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mechanisms that have been shown in terms of increase in, you know, inflammatory enzymes, and increase in alterations of redox potential that are some of the potential plausible biological mechanisms. Again, other people who are biological experts will opine on them and detract from the strengths and weaknesses.

Q. You have not done an expert review of inflammation evidence yourself; correct?

A. When you say -- I mean, expert review of inflammation.

MS. PARFITT: Object.

Q. You're deferring to other experts on the topic and subject of inflammation; is that right?

MS. PARFITT: Objection.

A. Yeah. I mean, other experts, I mean, I can look at the evidence and see, A, one, that inflammation plays a role in cancer. Two, inflammation plays a role in ovarian cancer.

At least my opinion is that, you know, talc can, you know, induce inflammation; others will provide more detailed opinion.

Q. In terms of the mechanism by which ovarian cancer may or may not be related to

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inflammation, you are deferring to other experts; correct?

MS. PARFITT: Objection. Misstates his testimony. He just told you --

MR. ZELLERS: I'm asking him the question. Okay?

MS. PARFITT: Counsel, he did answer it. And you just asked the question again and you misstated what he said.

MR. ZELLERS: Ms. Parfitt, please. I thought we had a discussion.

MS. PARFITT: We did.

MR. ZELLERS: We ought not to have speaking objections.

MS. PARFITT: We don't. But I'll tell you the discussion we did have. You can't misstate --

MR. ZELLERS: I'm allowed to ask the witness what his opinions are and are not.

MS. PARFITT: Absolutely. But not to misstate them. That's all. Let's ask it again.

THE WITNESS: I'm sorry. I forgot.

MR. ZELLERS: It was a question.

THE WITNESS: What was the question?

MR. ZELLERS: Can you read the

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question?
MS. PARFITT: Listen carefully to the question.
MR. ZELLERS: Okay. Again, Ms. Parfitt, let the witness handle himself. He's an experienced, capable person.
MS. PARFITT: Yes. I would certainly both agree with that. He's quite good.
(The question was read by the reporter, as requested.)
MS. PARFITT: Objection. Misstates his testimony.
A. No. To the extent that my causal question needs -- you know, evaluated the evidence on the link between, you know, inflammation, ovarian cancer and talc and inflammation, I can opine that, you know, this link supports my causal opinion. Whereas, to the precise details of such a link, I would obviously defer to other experts.
BY MR. ZELLERS:
Q. Not all inflammatory conditions lead to cancer; correct?
A. Yes. And there are pro-oxidant conditions and there are antioxidants. And I

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examined the evidence which relates to if there were -- you know, if talcum powder products, for example, had antioxidants or, in the Saed study, they increased the level of antioxidant enzymes, then that would be evidence against the link between redox potential and talc and ovarian cancer. So there are various pieces of the evidence.
Q. All of us experience inflammatory reactions of one sort or another, including chronic conditions, and they do not all lead to cancer; correct?
MS. PARFITT: Objection. Form.
A. Yeah. But it's the balance of -- you know, that is altered between pro-inflammatory and anti-inflammatory conditions and the pro-oxidant state and the antioxidant state in my understanding that, you know, is a plausible mechanism for talc in ovarian cancer. Again, based on my understanding. Others will provide details.
Q. Rheumatoid arthritis is an inflammatory condition; right?
A. Heart disease is -- everything is inflammation.

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Q. Rheumatoid arthritis doesn't increase the risk of ovarian cancer, does it?
A. I don't know that question. I have not evaluated it.
Q. Psoriasis does not increase the risk of ovarian cancer, does it?
A. For all, it could. We don't know that. We can spend time reviewing that. We can't answer questions.
Q. We're here to talk about the science; correct?
A. Yeah. So the science, you have to look -- I haven't looked at psoriasis and cancer. I haven't looked at, for example, rheumatoid arthritis increases cardiovascular disease, because I've looked at it. I can't answer questions that I haven't looked at.
Q. Have you done an expert review of the role of inflammation in causing ovarian cancer? Have you personally done that review?
A. No. I have just looked at, you know, what is the role of inflammation in ovarian cancer, and are there plausible biological mechanisms that either support or refute whether talc can induce inflammation.

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Q. How does an acute inflammatory response lead to cancer?
A. Yeah. I mean, and I'm not making a case for an acute inflammatory. I'm not sure. Did I state that? You know, this is a chronic inflammatory process.
Q. What evidence is there that externally applied talcum powder causes chronic inflammation?
A. Yeah. I mean, you know -- can you give me a second?
Q. Sure.
A. Yeah. I'm not aware of a study that talc specifically itself causes chronic inflammation.
Q. There are no reports in the literature of externally applied talc leading to inflammation, granulomas, fibrosis or adhesions anywhere along a woman's reproductive tract; correct?
MS. PARFITT: Objection.
A. Yeah. There are other studies that, you know, not externally applied.
Q. If up to 50 percent of U.S. women have used genital talc, shouldn't this be a common

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finding?
MS. PARFITT: Objection. Form.
A. So I'll step back and share with you what epidemiology.
Yeah. I mean, ovarian cancer, the incidence of ovarian cancer is, what, 11 by 100,000. It's a very rare cancer. Even if 50 percent use it, you know, it increases, you know, it affects it.
So we are not -- nobody is saying that, yeah, every woman who gets talc will get it. So just because there's an increased risk with talc, how much of the U.S. population should get ovarian cancer is a different question. That's not what I estimated.
That's -- you're asking a question about attributable risk and population attributable risk. Some have attributed it to 10 percent, 40 percent. I haven't done that estimation.
MR. KLATT: Move to strike. Nonresponsive.
MR. ZELLERS: Join.
Q. Granulomas, fibrosis or adhesions don't cause ovarian cancer; correct?
MS. PARFITT: Objection.
A. I'm not aware of precise biological

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mechanisms of, you know, ovarian cancer.
Q. Isn't the theory of inflammation as a cause of ovarian cancer an unproven hypothesis?
MS. PARFITT: Objection.
A. Well, it's a plausible hypothesis that, you know -- and it's well accepted that, you know, one of the mechanisms is inflammation.
Q. It's still unproven; correct?
MS. PARFITT: Objection. Misstates testimony.
A. Well, I'm not -- my standard wasn't looking at absolute certainty that, A, talc induces inflammation, and inflammation causes ovarian cancer. I'm looking for evidence for or against whether inflammation, you know, induces or reduces ovarian cancer.
Q. What studies or evidence do you cite in your report against the proposition or theory that inflammation is a cause of ovarian cancer?
A. Yeah. I think -- I'm sorry. The question was what studies --
Q. You told me it was important to cite both the studies that support your position and also the studies that refute your position; is that right?

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A. Yeah. And I think it's the studies on NSAIDs. I don't remember the precise -- I don't know if -- yeah. It's Ness or --
Q. I will and do intend to ask you a few questions about NSAIDs and about some of those studies.
A. I think that's where --
Q. Well, let me talk about or ask you a question about a study that you do cite in support of your inflammation opinion. You rely on -- is it Saed 2018 article?
A. Yes.
MR. ZELLERS: I'll hand you the Saed 2018 paper.
(Article entitled "New Insights into the Pathogenesis of Ovarian Cancer: Oxidative Stress" marked Exhibit 26.)
MS. PARFITT: Thank you.
MR. ZELLERS: We'll mark that as Deposition Exhibit 26.
BY MR. ZELLERS:
Q. This is a study that you cite in support of your position; is that right?
A. I don't know if I cite it as a support of my position. I cite it as an article that

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shares insight into the parthenogenesis of ovarian cancer. I mean, you know, he's the expert and he'll form his opinion.
So it's a study cited in my report. In fact, I won't even be able to discuss the details of that study with you.
Q. You're not comfortable discussing the details?
A. Yeah. I mean --
MS. PARFITT: Objection.
A. -- you can ask a question and I'll try to answer to the best of my ability. And if I won't, I'll be able --
Q. The point is, this is really an area for other experts; agreed?
A. Yes. This is an area for other expertise.
Q. Saed, that paper just looked at immortalized cell lines; is that right?
MS. PARFITT: Objection. Form.
A. Yes.
Q. The authors do not identify what either the positive or the negative controls were; is that right?
MS. PARFITT: Objection.

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A. So is this the study or is this just their review article?
Q. This is the paper that you cite to in your report.
A. Can you point out in my report which reference number is that? I know I've cited them, but I'm just trying to orient myself.
Q. Are you familiar with this paper? Have you looked at it before?
A. Yes. I have looked at this paper, but they also have other abstracts and other papers. I think that's what I was relying on.
Yeah. So I'm relying on this and 125, Saed.
Q. The authors in this paper that you support -- strike that -- that you cite and are relying on do not identify what either the positive or the negative controls were; correct?
MS. PARFITT: Objection. Misstates the evidence.
A. Let me just look at 125, and then I'll answer the question.
No. That's not 125.
Q. I'll move on and ask another question.
A. Sorry about that.
Q. That's all right.

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Saed references unpublished data; correct?
MS. PARFITT: Objection.
A. Yeah. And I've just been informed by counsel that it has been accepted for publication, but the data that I -- that I referenced were, you know, at the time, available as abstracts.
Q. Saed referenced -- references unpublished data that you rely on in coming up with at least some of the opinions in your report; is that right?
A. Yeah. I mean, it's one of the, you know, number of studies that I reviewed. It's not the only study on, you know, on biological mechanisms.
Q. Why doesn't inflammation generally, for example, in pelvic inflammatory disease, cause ovarian cancer?
A. Again, that's not -- you know, that is not -- I'm not going to be opining on the precise mechanisms of ovarian cancer in my testimony or my report. That's not my area of expertise.
Q. Why don't NSAIDs and aspirin use, which supposedly reduce inflammation, consistently reduce the incidence of ovarian cancer in chronic

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users?
A. Yeah. So I don't know if that's consistently. But as I mentioned earlier, and I may have cited it in this study, that when I talked about Ness, and I'm trying to find it, but, yes, there is, you know, NSAIDs have not been -- they don't consistently reduce the risk of ovarian cancer, but in some studies, they have shown to reduce the risk of ovarian cancer.
Q. If, in fact, inflammation was a causative factor in ovarian cancer, and if NSAIDs and aspirin use reduce inflammation, wouldn't you expect some consistency in the studies that would show NSAIDs and aspirin use reduced the incidence of ovarian cancer?
A. So, first of all, you're asking a broad question. Inflammation. What do you mean by that?
And I don't know -- yeah. Exactly. So I don't know the precise biological mechanisms of ovarian cancer. And just because the ovarian cancer-mediated inflammation is different from, you know, anti-inflammatory, so both may be entirely consistent, I'm not saying they are, but both mechanisms, you could have NSAID-induced

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reduce inflammation and NSAID-induced increase inflammation. That's just not what -- that area where other people will provide, you know, more testimony.
Q. If inflammation is the issue, why would cornstarch be a superior alternative to talc?
MS. PARFITT: Objection. Form.
Q. And to give you context, the FDA banned the use of cornstarch on surgical gloves because of the risk of inflammation, granulomas, fibrosis, adhesions and irritation; is that right?
A. I'm not aware of all the particular, you know, regulatory actions on cornstarch.
Q. Take a look at the FDA 21 C.F.R, parts 878, 880, and 895.
MR. ZELLERS: We'll mark that as Deposition Exhibit 27.
(Federal Register, Vol. 81, No. 243 marked Exhibit 27.)
BY MR. ZELLERS:
Q. If you look at the second page, first paragraph, last sentence, so I'm under executive summary. The last sentence in the last full paragraph.

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"However, the use of powder on medical gloves presents numerous risks to patients and healthcare workers, including inflammation, granulomas, and respiratory allergic reactions."
Did I read that right?
A. Yeah.
MS. PARFITT: Do you know where it is? Mm-hmm.
A. Okay.
Q. Why, then, given that, would cornstarch be considered a superior alternative to talc?
MS. PARFITT: Objection. Form.
A. Am I -- did I state in my -- I mean, you know, I'm not evaluating the causal role of cornstarch and, you know, its role in ovarian cancer. I'm not even aware of the existence of this document and what it pertains to.
I don't see any reference to cornstarch here. I don't evaluate how they regulate various products, whether it's food or cornstarch.
Q. Are you familiar with the term "confounding"?
A. Yes.
Q. That's where the presence of another association confuses the relationship between the

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exposure and disease being studied; correct?
A. I don't -- I don't think that's the definition of confounding.
Q. What is wrong with that definition?
A. Confusion is not an epidemiologic term. There's no such thing as confusion in epidemiology. You have bias. You have misclassification. You have measurement error.
Confounding is a case where you have a variable that's related to the outcome and that's, you know, maybe associated with the exposure and is not on the causal pathway between exposure and outcome.
And, you know, it creates an artifactual relationship between exposure and outcome.
Q. Confounding and confusion are similar terms; correct?
A. No. They're not. Confounding is a scientific term. Confusion is layman from that. I don't think it has -- at least in my term, I don't --
Q. So you disagree that confounding relates to the presence of another association which potentially confuses the relationship between the exposure and disease being studied;

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is that right?
A. I don't disagree -- what I am trying to define precisely confounding is that, you know, it creates a different relationship, had the confounder not been present, and I'm just trying to say how it does that.
It's associated with the outcome. It's associated with the exposure and not, you know, and not on the --
Q. Let's use an example, so we're sure we're talking about the same thing.
If you are studying the association between coffee and pancreatic cancer, you need to be mindful of whether cigarette smoking is more common in coffee drinkers than in the rest of the population; correct?
A. Yes.
Q. Cigarette smoking could be a confounder in that situation; is that true?
A. Well, so there are several parts to that. Just because it's more common in coffee drinkers does not make it a confounder. To make a confounder, you have to have three specific. What you're talking is, yeah, it's associated with coffee. But is it associated with

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pancreatic cancer? Is it on the causal pathway?
So a confounder is a very precise epidemiologic term. It's not just everything we pull off the air and say because it's associated with the coffee, it becomes a confounder.
Q. Listen to my question.
A. Sure.
Q. Cigarette smoking could be a confounder in my hypothetical; right?
A. If it was associated with pancreatic cancer and not present in the causal pathway and, obviously, associated with coffee.
Q. Because if more coffee drinkers are smokers than non-coffee drinkers --
A. It could be the other way around.
Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct?
A. Yes.
Q. Confounding can distort results in epidemiological studies; is that right?
A. Yes. And you have to adjust for confounding.
Q. Residual confounding is possible in every occupational study; is that right?

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MS. PARFITT: Objection.
A. Sorry. Can you repeat the question?
MS. PARFITT: Here it is.
Q. Sure. Residual confounding is possible in every observational study; correct?
A. Observational. Yeah.
It is possible; right? Is that what you said?
Q. Yes.
A. Yeah. Residual confounding is possible because you can't measure, you know, every variable that you can think of.
Q. And unmeasured confounders may be present in every observational study; correct?
A. Yeah. There's always the potential for unmeasured confounding. It doesn't mean that it exists.
Q. It's impossible to say that all known and unknown confounding factors have been controlled for in any given study; correct?
A. You don't -- you know, what you don't know, you can't control for.
Q. In this case, new factors possibly involved in ovarian cancer are just being published in the literature; is that right?

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MS. PARFITT: Objection. Vague.
A. Yeah. I don't -- I don't know what you're like -- just give me an example so I can --
Q. Okay. History of chlamydia infection and history of weight gain during adolescence are two recent examples that are being published in the literature as factors possibly involved with ovarian cancer; correct?
MS. PARFITT: Objection. Form.
A. I haven't seen them. But I mean, weight gain has been adjusted for in several of the analyses. So I don't know about that. Yeah.
Q. Well, let's assume --
A. We're talking about chlamydia.
Q. Let's assume that that's correct.
Those factors, history of chlamydia infection and history of weight gain during adolescence, those factors were not controlled for in any of the published talc-ovarian cancer studies, were they?
MS. PARFITT: Objection. Form.
A. Yeah. So if they're not known, first of all, you have to evaluate and, you know, is that a true -- true association?

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But most importantly, just because, A, first of all, are they associated with the outcome? Then you have to ask, are they causally associated, and they would have to be associated with the exposure talc to be considered a confounder, just because they're a risk factor. Every risk factor need not be controlled in a study. You have to be associated with the exposure to, you know, consider the confounder.
That is the precise definition of confounding, is you have to be associated with the exposure. You have to be associated with the outcome. And you can't be on the path.
So just because chlamydia -- let me finish. Chlamydia, A, has a risk factor of ovarian cancer. If I design a study tomorrow for X and ovarian cancer, you know, I'm not going to consider it a confounder for my analysis.
Q. Confounders can distort the results in epidemiological studies; correct?
MS. PARFITT: Objection. Form.
A. Yeah. We've discussed that, I think.
THE WITNESS: We'll take a break. If you want to finish this confounding thing.
MR. ZELLERS: No. We can take a break

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now.
MS. PARFITT: Good. Thank you.
THE VIDEOGRAPHER: This ends Media 3. Off the record, 2:17 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Here begins Media No. 4 in today's deposition of Sonal Singh, MD, M.P.H. Back on the record, 2:29 p.m.
BY MR. ZELLERS:
Q. Dr. Singh, in your report, at Page 54, Paragraph 7, you address the subject of confounding in studies of talcum powder use and ovarian cancer; is that right?
A. Yes.
Q. On Page 54 of your report, you state, "Although there are some risk factors for ovarian cancer," and then it continues, "for any of them to be confounding to an extent that could account for the positive relations that have been reported, they would have to be strongly correlated with talc use. Family history, ethnicity, obesity and some reproductive risk factors are positively associated with the risk of ovarian cancer, but the magnitude of these associations does not appear high enough to

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introduce enough confounding either jointly to explain completely the positive associations."
And it should be the positive association.
A. Yes.
Q. Is that the statement that you make?
A. Yes.
Q. There's no citation for that statement; is that right?
A. Yes. But partly because I couldn't find evidence -- and, you know, about the risk of talcum powder use and these risk factors. And so that -- so the issue that I -- prior to the statement, states that -- these other risk factors, which we know are risk factors for ovarian cancer.
Q. Is this your statement that you made here?
A. Yeah. Let me just explain what I did here.
Q. That was a simple question.
A. Yeah. It is my statement.
Q. Have I read your statement?
A. Yes. But it is about the fact that we don't have, you know, family history, ethnicity, obesity and reproductive factors associated, but

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these associations, as it relates to talc use, we don't have data on how these -- to be considered a confounder, they have to be associated with talc use. We don't have data on that.
Q. My question just is: Did you write that?
A. I did. Yeah.
Q. All right. Now, do you know who Ken Rothman is?
A. Yeah. He has written a textbook on epidemiology.
Q. He is a well-respected epidemiologist; is that right?
A. Yeah. He's well respected.
Q. He has written a textbook on epidemiology that's widely recognized as one of the best; is that right?
MS. PARFITT: Objection.
A. It is nice. I mean, I have a copy of it.
Q. I've looked at your report and your reliance list. In terms of your reliance list, you do not cite to a paper by Ken Rothman and others published in 2000 entitled "Interpretation of Epidemiologic Studies in Talc and Ovarian

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Cancer"; is that right?
A. If I haven't, then I haven't. Yeah.
Q. You did put it on your additional materials and data considered.
Do you see that?
A. Yes.
Q. It's on the last page.
MR. ZELLERS: I'm going to mark that paper as Exhibit 28.
(Document entitled "Interpretation of Epidemiologic Studies on Talc and Ovarian Cancer" marked Exhibit 28.)
MS. PARFITT: Thank you.
MR. ZELLERS: You're welcome.
BY MR. ZELLERS:
Q. Do you see Exhibit 28 in front of you?
A. Yes.
Q. Exhibit 28 is an article prepared by Kenneth Rothman entitled "Interpretation of Epidemiologic Studies of Talc and Ovarian Cancer."
Is that right?
A. Yes.
Q. Take a look at Page 5 of that paper,

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the second paragraph.
Do you see where --
A. Confounding, you're talking about?
Q. Yes. Where Rothman discusses confounding?
A. Yeah.
Q. Other than the list of four risk factors in parentheses, you just copied the language from Dr. Rothman's article and pasted it into Page 54 of your report; correct?
MS. PARFITT: Objection.
A. No.
Q. All right. Do you have your report in front of you, Page 54?
A. And you say that I don't cite this article or --
Q. If you don't cite that article, you have just testified under oath that these are your words in your report.
So take a look at Page 54 of your report. Take a look at Page 5 of the Rothman paper.
A. Yeah. I mean, you know, I may have -- I think I'm talking of different risk factors.
Q. Doctor --
MS. PARFITT: Let him finish, please.

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MR. ZELLERS: Okay.
A. I may have failed to cite that article. You know, it's okay. I mean, it's not okay, but I'm just saying I may have failed to cite that article.
Q. Do you agree that the entire first part of Rothman on confounding that you have cited word for word in your report, and you can start with "although there have been some strong risk factors for ovarian cancer, for any of them to be confounding."
A. Yeah.
Q. If you read the rest, all the way through the next couple of sentences, down to "positive association," it's --
A. Yeah.
Q. -- word for word; right?
A. Yeah. I wouldn't say I copy and pasted. I would say that I have not referenced it.
Q. You copied and pasted it.
A. No. I did not. I read it, and I wrote it. And I did not reference it.
Q. You didn't write it. It's exactly word for word from the Rothman paper --

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A. No. It isn't.
Q. -- with the exception of you added, in parentheses --
A. Yeah.
Q. -- "genetic risk factors, family history, obesity and reproductive history"; is that right?
A. Yeah. And I didn't cite it, but -- so you look at a study and a paper, and, you know, I wrote it. And I was remiss in not citing it. I didn't copy and paste it.
Q. Well, you copied it word for word; correct?
A. I did not.
MS. PARFITT: Objection. Misstates his testimony.
A. I'm saying what I did. But I did not cite it.
Q. The fact are the facts.
A. Well, the facts are that the content is different and I did not cite it.
Q. What content is different other than you adding in --
A. The risk factors.
Q. -- parens, "Example, genetic risk

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factors, family history, obesity and reproductive history," what else is different? Show me one word that is different --
A. Yeah.
Q. -- between what you've written here and what is written by Rothman in his paper.
A. Yeah. It isn't, and I should have cited it.
Q. All right. The paper by Rothman and others -- well, strike that.
A. And where was this published, just -- I mean, it doesn't have a citation in it.
Q. If you're going to copy it word for word --
A. I did not.
MS. PARFITT: Excuse me. Object to the question. Don't be argumentive, Counsel. He said he didn't cut and paste it. He said he failed to cite it. That's his testimony.
A. You can, you know, go forward and say that.
Q. The question is: You don't know -- let me withdraw that. You're looking at something.
A. Yeah. Go ahead and ask the question.
Q. You thought that this was a reliable

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source; correct?
A. Yes. And I did not cite it.
Q. The Rothman paper, Exhibit 28?
A. Yes.
Q. All right. Now --
A. Well, it's a source. I mean, it's in with other source that I rely on.
Q. At least in these couple of sentences --
A. In the paragraph.
Q. -- you agree; correct?
A. Yeah.
MS. PARFITT: Agree what? Agree what?
Q. Agree that the -- the two sentences from Rothman are the same two sentences as in his report and does he agree with those two sentences?
A. Well, obviously, the risk factors are different, because I know more about the risk factors since 2000. And -- but the point that I'm trying to make, and as you can see the language is the same, and it should have been cited.
Q. You told us throughout this deposition that it's important for you to be -- as an

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expert, to be fair and to cite information, positions on -- that both support and refute your position and plaintiffs' position; correct?

A. Well, it's not about their position, support or refute the causal hypothesis.

And I'm agreeing that I was remiss in not citing this.

Q. You also did not cite the next sentence of Rothman --

A. Yes.

Q. -- which states, "Of course, it remains possible that yet unidentified risk factors for ovarian cancer could be important confounders, and several such factors in the aggregate could give risk to an overall association as weak as the one between talc and ovarian cancer."

You did not cite that; correct?

A. Yeah. And -- but that is already expressed. The same factor is also expressed in the first sentence. Confounding is one potential explanation for -- so, you know, again, if I had placed that sentence, you would say that, well, you're taking three lines, four.

So I cite that confounding is one potential explanation.

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Q. You don't disagree with that statement.

A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.

Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based, case-control studies subject to recall bias which can readily give rise to associations of this magnitude."

Did I read that correctly?

A. Yes.

Q. Go to Page 4, third paragraph of the Rothman paper, Exhibit 28. I'm looking at the section under "recall bias," and the third sentence, "Recall bias can easily introduce enough bias to produce the modestly sized overall effect, relative risk equals 1.3, that emerges from these studies."

MS. PARFITT: The only correction --

Q. Is that what Rothman wrote?

MS. PARFITT: I'm sorry. It does say "can readily."

MR. ZELLERS: I'm sorry.

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MS. PARFITT: No worries. No worries.

A. Which line are you in there?

Q. Sure. Look at "recall bias." Does the third sentence state, "Recall bias can readily introduce enough bias to produce the modestly sized overall effect, relative risk equal 1.3, that emerges from these studies"?

A. That's -- yeah, that's his interpretation.

Q. You don't disagree with that, do you?

A. Well, I do disagree in the sense that, you know, he's making inference on the magnitude. I'm not disagreeing that there's a potential for recall bias. But, you know, as I've discussed in my report and -- and, again, if you say that, then I should be writing the Rothman paper instead of my report. Right? You would want Ken Rothman to testify.

You have to, you know, take -- you know, I understand what he's trying to say. He's saying that recall bias can introduce an element that would produce 1.3.

Q. In fact, Rothman and the other authors of this paper conclude that the modest positive association --

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A. Yeah.

Q. -- seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?

A. Yes.

Q. You did not note in your report Rothman's conclusion -- and if you turn to Page 8, his conclusion -- "More important, there is also positive evidence against a causal association. The inverse dose-response trend for both duration of use and frequency of use, a pattern that could not be explained by a causal relation. Based on these considerations, we suggest that the evidence to date does not indicate that talc can be 'reasonably anticipated to be a human carcinogen.'"

A. Yes. And this report was prepared on November 8, 2000. That's 20 years ago. And we have many other studies subsequent to that talking about dose-response, several other understandings about biological mechanisms.

So if I wanted -- if you want me to just cite to the Rothman paper or -- there are 115, you know, papers. I mean, there are other -- others will have opined that talc doesn't cause

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ovarian cancer.
Q. What methodology did you use to rule out the effect of an unidentified confounding bias or multiple unidentified confounding biases?
A. Yeah. So I mean, as the meta-analyses have shown, there are no differences between -- most of the studies show no differences between adjusted and unadjusted estimates, suggesting that the potential for confounding is minimal.
There is no way to rule out unmeasured confounding. And that's always a possibility. It doesn't mean that it exists.
Q. As we discussed earlier, you did review the Gertig 2000 paper and cite it in your report; is that right?
A. Yes.
Q. On Page 48 of your report, you note that Gertig 2000 found a statistically significant increased risk for ever talc use for serous invasive cancers; correct?
A. Let me just come to that section.
Yes.
Q. Gertig did not control for BMI or for cigarette smoking, did it?
A. And I'm writing age, duration of

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contraceptive use, BMI, smoking status.
Can I look at the study? Sorry.
Q. You're not wasting my time, are you?
A. No. No. Because my writeup says that. I may be incorrect. And I just want to make sure that my writeup is -- you know, if we need to correct it, I need to correct it. I'm sorry.
MR. TISI: Did you mark it?
MR. ZELLERS: No.
THE WITNESS: I'm not wasting it, I'm saying that because writeup -- I say that it does.
MS. PARFITT: Just so you know, mine is a marked-up copy of it.
MR. ZELLERS: I'm not going to mark it. I'm not going to look at it. I just want the doctor to answer the question.
MS. PARFITT: Sure. Here's a copy of Gertig.
BY MR. ZELLERS:
Q. And my question is very simply --
A. Age and smoking.
Q. -- Gertig -- yes -- did not -- well, BMI --
A. Yeah. It says it conducted for

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cigarette smoking and BMI.
Q. That it did control for that?
A. Yeah.
Q. All right. Show me where, in Gertig 2000, that they state that they did control for BMI and for cigarette smoking.
A. "For age-adjusted analysis, we categorized values as oral contraceptive use, tubal ligation, post-menopausal, cigarette smoking and BMI."
Q. What page?
A. That's two -- whatever that page is, 250. Yeah. That's my understanding.
If you look at Table 1, they do have, you know, cigarette smoking and whatnot. That's my understanding.
Q. Ter Riet 2013, you cite that in your report; is that right?
A. It is.
Q. Terry 2013 did not adjust for a hormone replacement therapy usage; correct?
MS. PARFITT: Here is Ter Riet.
A. Just let me go back to my report. This is the Ter Riet meta-analysis?
Q. Yes. Ter Riet 2013, meta-analysis.

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A. Okay.
Q. The question is: Did Ter Riet 2013 adjust for hormone replacement therapy usage?
A. Ter Riet.
MS. PARFITT: Here is a copy.
A. Mine doesn't say that. Usually, Table 1 should answer that question.
HRT, right? I don't have that data, and I haven't included it in my report.
Q. If hormone replacement therapy is a risk factor for ovarian cancer, and assuming that Ter Riet did not account for that, that is a potential confounding factor; correct?
A. Again, I have a slight difference in your and my definition of confounding, that you would have to obviously know if there is an association with talc exposure for it to be considered a confounder in that specific study.
Q. All right. You cannot say whether the odds ratio of Ter Riet 2013 in that study would have been lower if the authors had adjusted for hormone replacement therapy usage; correct?
MS. PARFITT: Objection.
A. Or higher. I mean, we cannot say one way or the other.

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Q. Recall bias, it's a concern in every retrospective study; is that right?
A. Yeah, it is a potential concern in design of studies where, you know, you're asking about past exposure.
Q. Recall bias can distort a scientific evaluation of whether an exposure is actually related to a disease; correct?
A. Yes.
Q. For example, recall bias could distort results if women with ovarian cancer were more likely to remember their exposure to talc than women without ovarian cancer; correct?
A. Yes. I mean, but the extent here is quite minimal, because we don't see it with a -- you know, for daily use, you know, the likely magnitude is small. We've talked about that.
You know, if recall bias was operational, we would see it with nongenital talc use. They would be reporting that. And we would be seeing it with other types of, you know, cancer beyond, you know, ovarian.
So, yes, recall bias is a potential, but the likely magnitude is small.
Q. On Page 54, Paragraph 6 of your

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report -- do you have Page 54, Paragraph 6?
A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in Rothman's study, doesn't mean that it's, you know --
Q. I have a new question. Are you ready?
A. No. I mean, I have to finish my last question.
Q. I didn't ask you a question.
A. Okay. Because we are still on the topic of recall bias.
Q. I asked the question.
A. Okay.
Q. Recall bias could distort results of women with ovarian cancer were more likely to remember their exposure to talc than women without ovarian cancer; correct?
A. Yes.
Q. The next question is: Can you turn to Page 54, Paragraph 6 of your report?
A. Okay.
Q. You state, "case-control studies are susceptible to recall bias, particularly when data on exposure are self-reported. However, several studies have included these questions on

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talc exposure as part of larger questionnaires on other risk factors, minimizing the possibility of recall bias."
Did you write that?
A. Yes.
Q. How does asking about other risk factors minimize recall bias as to a particular risk factor?
A. Yeah. Because, you know, you're not stimulating them to answer -- you know, if you're asking them ten questions about, say -- so it's like, well, were you -- you know, were you active, were you using oral contraceptives, were you -- so if you are -- let me finish. Let me finish my explanation.
You're introducing the question of talc use within ten different questionnaires, then you minimize the possibility of recall bias for that particular product versus you're asking talc alone.
Q. On what literature are you relying to say that asking about other risk factors minimizes recall bias as to another risk factor?
A. I mean, that's just my general understanding of epidemiology. And maybe, you

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know -- yeah, it's not -- I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know -- yeah, recall bias.
Q. Are you done?
A. Yeah.
Q. All right. Let's look at the effects of recall bias in a study on talcum powder use in ovarian cancer.
Are you familiar with the Schildkraut 2016 study?
A. Yes.
Q. That was one of the studies that you relied on in forming your opinions; is that right?
A. Yes.
MR. ZELLERS: Let's mark that study as Deposition Exhibit 29.
(Article entitled "Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES) marked Exhibit 29.)
MS. PARFITT: Got it. Thanks.
BY MR. ZELLERS:
Q. This is a study titled "Association

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Between Body Powder Use and Ovarian Cancer; The African American Cancer Epidemiology Study"; correct?
A. Yes.
Q. The study looked at, among other things, what impact, if any, lawsuit filings in 2014 had on whether women recalled using talc in the past; correct?
A. Yeah. It examined the issue of stimulated reporting. And I note it in my report. I don't -- I don't discount that in my discussion of the Schildkraut study.
Q. We'll call it Schildkraut. Can we do that?
A. Whatever. I don't know.
Q. The authors in that study, Exhibit 29, thought that the publicity from lawsuits might influence the participants' recall of prior body powder use; is that right?
MS. PARFITT: Objection.
A. Yes. And I noted on Page 45 of my report that although there was some evidence that there was more reporting after class action lawsuits in 2014, recall bias alone is insufficient because there is a statistically

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significant risk both before and after 2014. But the authors did, you know, think it was an important thing to look at.
Q. The authors looked at this and tried to study this; is that right?
A. Yes.
Q. All right. Go to Page 4, Table 2 of the Schildkraut paper. Tell me when you have it.
A. I do.
Q. This is a table, Adjusted Odds Ratios for the Associations Between Mode, Frequency and Duration of Body Powder Use and Ovarian Cancer; is that right?
A. Yes.
Q. The second column shows the number of cases. That's women with ovarian cancer; correct?
A. Yes.
Q. The third column shows the controls. That's the women who do not have ovarian cancer; correct?
A. Yes.
Q. Looking at the data, before 2014, before the lawsuits, the percentage of controls, meaning women without ovarian cancer, who said

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that they used talc on their genitals was 34 percent; is that right?
A. Where is that? Yeah.
Q. The percentage of cases, meaning women with ovarian cancer, that said that they used talc on their genitals was 36.5 percent; is that right?
A. I'm just looking at this. Give me a second.
36 -- interview data after 2004?
Q. No. My question here is: For women who were interviewed before 2014 --
A. Mm-hmm.
Q. -- the control, so women without ovarian cancer, they stated they used talc on their genitals, 34 percent; is that right?
A. Yes.
Q. For that same time period, women interviewed before 2014 --
A. Mm-hmm.
Q. -- with ovarian cancer that said that they used talc on their genitals was 36.5 percent.
A. Yes.
Q. Is that right?

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So roughly the same reporting of genital talc use between women with and without ovarian cancer occurred before the lawsuits were filed in 2014.
MS. PARFITT: Objection.
Q. Correct?
A. I don't know the timing of lawsuits, but yes, 2014.
Q. So then let's look at what happened after the lawsuits were filed.
After 2014, what percentage of women without ovarian cancer said that they used talc on their genitals?
A. The case -- are you talking about cases or controls?
Q. Yeah. I'm talking about controls.
A. 34.4, 34.4.
Q. So based on this data, the lawsuits had essentially no effect on how many of the women without ovarian cancer, the controls, remembered or recalled using baby powder; correct?
A. Yes.
Q. It was 34 percent before 2014 and 34.4 percent after; is that right?
A. Yes.

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Q. For women with ovarian cancer, before the lawsuits were filed, 36.5 percent of them said they recalled using baby powder; correct?
A. Yes.
Q. But after the lawsuits were filed, the percent of women with ovarian cancer who said they used baby powder went up to 51.5 percent; is that right?
A. Yes.
Q. So after the lawsuits were filed, the percent of women with ovarian cancer who said they used baby powder jumped by over 40 percent; is that right?
MS. PARFITT: Objection. Form.
A. By 40 percent? Where is 40?
Q. A difference between the 36. --
A. 10 percent. It's 51 and 34. Right?
Q. It jumped -- I don't have a calculator.
A. You're subtracting 51 to 36 or 51 to 34?
Q. Well, there was --
A. Sorry.
Q. That's okay. It's late.
There was a significant increase --
A. There was an increase.

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Q. -- from 36.5 percent before the lawsuits were filed to 51.5 percent after; is that right?
A. Yes.
Q. So, suddenly, women who had ovarian cancer started reporting a higher incidence of talc use than women had reported before 2014; is that right?
MS. PARFITT: Objection. Form.
A. Yes. There was -- there was incidence -- you know, evidence of stimulated reporting. But that is just one element of recall bias. That's not completely what is being addressed in my statement on recall bias. This is evidence about stimulated reporting, which is one -- one spectrum of recall bias.
Q. It's at least an example of the potential effect of recall bias; correct?
A. Yes.
Q. All right. Go to Page 45 of your report, the last sentence.
A. Yes.
Q. "Although" -- and I'm quoting you. "Although there was some evidence that there was more reporting of genital powder use after class

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action lawsuits in 2014, recall bias alone is insufficient to explain these findings, because there was a statistically significant increased risk both before and after 2014."
Is that what you state?
A. Yeah.
Q. Let's look at what the study actually shows. So go to --
A. Yeah. I correct it. Should be there was an excess risk, because there was no statistically significant.
Q. Your report is in error; is that right?
MS. PARFITT: Objection.
A. Well, it should be corrected to an excess risk.
Q. It is not, and there is not a statistically significant risk; is that right?
MS. PARFITT: Objection. Form.
A. Yeah. The test for effect modification by year of interview was technique, but the particular estimate for above -- for, you know, for before 2014 was not significant.
Q. Exactly. So pre-2014, there was an odds ratio of 1.19 with a confidence interval ranging from .87 to 1.63; is that right?

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A. Yeah. Yeah.
Q. That is not statistically significant; is that right?
A. Yes.
Q. In the absence of statistical significance, that can be indicative of no risk existing; correct?
MS. PARFITT: Objection. Form.
A. Yeah. But, you know, I'm opining on the study as a whole. That's just one element of stimulated reporting in that study, you know. Yeah. So there's an excess risk, which is in the same direction, but not statistically significant.
Q. If the study had ended before 2014, it would have found no statistically significant relationship between talcum powder and ovarian cancer; is that right?
A. I'm not seeing the study. I have to interpret the whole study; right?
Q. Well, based upon this data that we just looked at --
A. Yeah.
Q. -- had the study ended before 2014, there was not a statistically significant

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relationship between talcum powder use and ovarian cancer; correct?
MS. PARFITT: Objection. Misstates the data.
A. Yeah. There was an excess risk which was not statistically significant. But, you know, we are picking and choosing analysis by 2004. Again, we talked about we are choosing by duration. You can pick any one of these analyses to cite it. You have to look at the cumulative evidence and the cumulative evidence from meta-analyses.
Q. How did you account for this recall bias in weighing the Schildkraut study?
MS. PARFITT: Object to the form.
A. So, again, I did not weigh one individual study. My weight of evidence is based on the meta-analysis and the cumulative evidence from meta-analysis, the biological studies, animal studies, human studies.
So, you know, I point out the limitations of the individual studies, as do the authors of the meta-analyses.
Q. Are your opinions in this matter dependent on talcum powder containing asbestos?

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A. No. I arrived at my causal opinion independent of, you know, presence of asbestos or, you know, or my understanding of the constituents. But I asked to better understand what are the constituents of, you know, talcum powder products.
And I was, you know, some of the documents and some of the literature even suggests and shows that, and some of the testing and some of the deposition testimony that I have been privy to, suggests the presence of asbestos in talcum powder product.
Q. Do you believe that talcum powder that does not contain asbestos causes ovarian cancer?
A. Yes.
Q. Is it fair to say that you have not made any independent determination as to whether or not the talcum powder products manufactured by J&J Consumer Products are contaminated with asbestos?
A. Yes. I have not made a determination. I've looked at the literature. I have looked at the testimony of the experts that was provided, and I've looked at testimony -- sorry -- the report of Dr. Luongo and I have relied on their

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reports for that.
Q. You have no personal expertise with that; correct?
A. No.
Q. Did you consider any testing that found no asbestos?
A. Yeah. I did. I think I'm citing the FDA report in my assessment that there are studies that suggest the -- I don't know if it's an FDA report. It's an FDA study that talks about it.
Q. If your assumption about contamination of talcum powder products with asbestos were not true, would your opinions in this case change?
MS. PARFITT: Objection. Form.
A. Well, again, you know, this is a weight of evidence that, does it, you know, contain talcum powder -- I mean -- does talcum powder product contain asbestos? Or, you know, these other metals we've talked about.
But my opinion was, in fact, arrived at before even I was aware of both of the deposition testimony, as well as the results of testing by Dr. Luongo that my causal opinion was that they caused, you know, ovarian cancer.

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MR. ZELLERS: Move to strike as nonresponsive. I'm going to ask the question again.
THE WITNESS: Sure.
BY MR. ZELLERS:
Q. If your assumption about contamination of talcum powder products with asbestos were not true, would your opinions in this case change?
A. No.
Q. In support of your opinion that talcum powder products contain asbestos, you cite to exhibits from the depositions of John Hopkins and Julie Pier; is that right?
A. Yes.
Q. Are you aware that those exhibits were created by plaintiff attorneys?
MS. PARFITT: Objection. Misstates the evidence.
A. Yeah. I mean, I asked them whatever that -- you know, these are -- as I understand them, they are, you know -- they are created as a part of the testimony of these deponents on behalf of, you know, the defendants. That's my understanding.
Q. Were you told that the exhibits

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Exhibit 28 to the deposition of John Hopkins and Exhibit 47 to the deposition of Julie Pier were exhibits that were created by plaintiffs' attorneys?

MS. PARFITT: Objection. Completely misstates the evidence in this case.

A. You know. I asked for constituents. I don't know what -- who created what. So I mean, I'm not going to be able to answer that type of question, who created this.

I was asked for, you know, what are the constituents, that can I learn more about this?

Q. Outside of your work in litigation, do you normally rely on documents created by advocates in order to evaluate epidemiological data?

MS. PARFITT: Objection. Again, misstates the evidence as to origin of the Hopkins and Pier Exhibits 28 and 40.

You may answer.

A. Yeah. I mean, I do. As I said earlier, I rely on our published data. And as the Health Canada approach states, that we rely on whatever evidence becomes available, and, A, is relevant to the particular testimony.

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And, importantly, just as my causal opinion was arrived at independent of the constitution of asbestos in talc, Health Canada also is unaware of the presence of -- or at least, you know, they haven't assessed the presence of asbestos in talc, and they are, you know, both congruent.

Q. Your testimony is that outside of your work in litigation, that you normally do rely on data and documents created by plaintiffs' counsel?

MS. PARFITT: Objection. Form. Asked and answered. And misstates the evidence.

A. So I, you know, rely on evidence that's available in terms of epidemiologic evidence. And my testimony on asbestos was based on testing and based on -- testing by -- based on some of, you know, there are studies which suggest the presence of asbestos.

Q. Do you know where the data in Exhibit 28 to Hopkins and Exhibit 47 to Pier came from?

A. You know, I was seeing these were in various mines conducted. That's my understanding.

Q. Do you have an understanding, other

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than from communicating with plaintiffs' counsel?

A. I'm not sure what -- so --

MS. PARFITT: I'm going to object to the form.

Q. Sure. The source of data?

A. Like source of --

Q. I'm asking you if you know where the data in those exhibits came from.

A. So I'll try to answer to the best of my ability.

My understanding is that the data on J&J and Imerys were from mines tested over the years, ranging, you know, from several decades. And that contained or -- you know, were contaminated with asbestos, various fibers that were created.

And the second was the Luongo report was products that were purchased and that were tested in the laboratory. So that's where the source. I mean, I assume these other two sources.

Q. Have you made any effort to investigate the alternative explanations for the data in those charts, Exhibit 28 and Exhibit 47?

A. I mean --

MS. PARFITT: Objection.

A. So, for example, I think that those

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data are, as I said earlier, my causal opinion is -- is, you know, this is only a -- my causal opinion is only -- you know, this is only a small link in my causal opinion between talc and ovarian cancer, and it's not predicated on the presence of asbestos.

I don't have the expertise to determine whether asbestos is present.

Q. I'm trying to make it a simple question. I'm just trying to find out what you did and what you did not do.

Did you make any effort to investigate the alternative explanations for the data in the charts which are marked as Exhibit 28 and Exhibit 47?

A. So --

MS. PARFITT: Objection.

A. What is 28, 47?

MS. PARFITT: Yeah. Let's get them. Do you have a copy of them here to show --

MR. ZELLERS: No.

MS. PARFITT: You aren't going to show it to him?

MR. ZELLERS: He cites to these in his report.

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MS. PARFITT: Then let's get them. We'll get them. Give him a moment.
MR. ZELLERS: We don't need to get them to answer this question.
MS. PARFITT: Do you need them, Dr. Singh?
THE WITNESS: Yes.
MS. PARFITT: Do you want to take a quick break?
MR. ZELLERS: And I object. And this should not be time that gets charged me.
BY MR. ZELLERS:
Q. My question simply is: Did he attempt to investigate any alternative causes. He can either say yes, he can say no, or he can say I don't recall.
A. Yes.
Q. All right. What did you do to investigate alternative explanations?
A. I mean, you know, I was looking at the -- I was already looking at the published literature, but beyond that, I was looking at what are the alternate -- again, as I said, you know, my expertise in determining -- I'm not a mineralist that I can, you know, that I can

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determine that. And, again, I'm not opining that Dr. Luongo's report -- I mean, he will have to vouch for his report.
Q. Let me ask it a different way.
A. Yeah.
Q. If scientists from the J&J companies and Imerys scientists say that those tests don't actually show asbestos, it was just tremolite reported, for example, you have no expertise to dispute that; correct?
MS. PARFITT: Objection. Misstates the evidence in this case, entirely.
Do you want to ask him a hypothetical?
Q. It's a hypothetical question.
MS. PARFITT: It's a hypothetical.
A. Again, with my limited expertise and my understanding of whatever I was provided and cited there, my understanding was that there was asbestos present in there and, you know, other people can have different opinions and I think mineralogists, geologists will --
Q. Those are the --
A. Yeah.
Q. -- expertise or the -- those are the types of experts that would have substantive

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knowledge on these issues; correct?
A. Yeah. I mean, for my purpose, you know, it was more an understanding of the constituents, whether that would provide, you know, proof against biologic plausibility, proof for biologic plausibility.
So, for example, you say, did I undertake attempts to understand the constituents? Yes. I mean, I was looking for, well, are there some antioxidants that, if you had some antioxidants in that product, and I'm not aware of, or anti, you know, carcinogens and maybe these scientists will be able to provide that.
Q. Did you ask counsel for plaintiffs for any information or testimony from either J&J company folks or Imerys scientists as to what the tests actually showed with respect to asbestos?
MS. PARFITT: Other than Exhibits 28 and 47?
A. I assume those testifying were J&J scientists and Imerys, and they were speaking about those tests.
Q. My question is: Did you ask for any additional information?
A. No. I mean, I asked -- as I said, I

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asked about the causal question and I got what I got. We can go about it in various ways.
Like did I ask again? No, I didn't. And I don't want any more documents.
Q. We'll try to shortcut this.
Do you believe Luongo? You reviewed his testimony; right?
MS. PARFITT: Objection. Form.
Go ahead.
A. Yeah. It's like how do you believe, you know -- again, it's an area of expertise. He tests, you know, these products, you know, this is not my area of experience. At least based on his testing, there is presence of asbestos in my -- and provides additional support.
Q. Did you look at any of the experts for the defendants who have opined to the opposite statement or the opposite?
MS. PARFITT: I think -- objection.
A. I was told that the expert defendants hadn't even been -- you know, haven't submitted reports or haven't been, you know, opined on. That's sort of my understanding.
Q. You believed and accepted the Luongo testing for purposes of this case; is that right?

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MS. PARFITT: Objection. Misstates the heart of his testimony.

A. So, first of all, this report is 70 whatever pages. Luongo is maybe a paragraph or two. So, yes, I believe that was one study.

For the purposes of, you know, identifying, you know, I identified his. I identified what was shown and what was in those notes. And I identified some epidemiologic -- I mean, some findings in the published literature.

I mean, that's as much as I could know about it. I mean, you had Routers' study, you know, talking about it in the media. So there's lots of different things.

I didn't go and, you know, go looking into the Routers report. Maybe that's what I should be looking at.

Q. You did not confirm that any of the talc samples mentioned in those charts were actually from talc that was used in baby powder; correct?

MS. PARFITT: Objection. Misstates the evidence that was available to him. If you want to show him the charts, you can do it.

Q. Can you answer that question?

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MS. PARFITT: Objection.

A. I did not confirm it myself.

Q. You realize that the vast majority of talc isn't even used for body powder; correct?

MS. PARFITT: Objection. Misstates the evidence.

A. I realize that -- yeah, I don't know what -- you know, there are various other uses of talc.

Q. Do you also rely on -- well, strike that.

How many Luongo reports have you reviewed?

A. I just have to take a look. I know that I reviewed one. And I'm not trying to slow you down. I'm just trying to be accurate.

Q. I think you are, but --

MS. PARFITT: Objection to the characterization, Counsel.

A. I'm trying to find this.

MS. PARFITT: He's acted in a professional way throughout all this, so it's good.

MR. TISI: You asked him questions looking at his report.

MR. ZELLERS: The witness said to me,

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I'm not trying to slow you down.

MR. TISI: And you said you think he was.

MR. ZELLERS: Yes. And it was in jest, Counsel. We all chuckled and we all laughed.

MR. TISI: As long as it was in jest, that's fine.

THE WITNESS: I took it to be in jest.

I know I reviewed one, but I'm just trying to see if I reviewed another one. There was -- yeah.

So I said, No. 30 and then 31, 32, two additional reports. Sorry.

Q. Have you ever met Luongo?

A. I don't know him.

Q. Do you know his qualifications?

A. No.

Q. Had you ever heard of him before you got involved in this MDL talc ovarian cancer litigation?

A. No.

Q. Have you reviewed any Luongo testing where he did not find asbestos?

A. These were the three reports I reviewed. So I don't know if he has conducted

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additional testing.

Q. Let me ask again. Have you reviewed any Luongo testing where he did not find asbestos?

A. I did not review any additional beyond what is cited here.

Q. Have you reviewed the FDA's testing of talcum powder products?

A. I have cited it. I mean, I have not reviewed the specific test, but I have, you know, cited what -- what they -- what they found.

Q. Have you made any effort to quantify the amount of any alleged contaminant in the Johnson & Johnson Consumer Products talcum powder products?

A. That's way beyond my expertise.

Q. Is any amount safe?

MS. PARFITT: Objection.

A. Well, as of my understanding that asbestos, you know, any amount of asbestos is not safe, that's my understanding. And, obviously, others can --

Q. Do you defer to other experts on that issue?

A. Yeah. But, you know, my understanding

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is that any amount -- and I think there's some testimony from others to that effect as well. But I'll defer to others.

Q. Do you have an opinion on what type of asbestos is in the baby powder products?

A. Again, you know, this whole -- you know, this sort of questions around constituents of the product, for me, it was more trying to understand whether it's asbestos or any other constituents in the product, provide evidence in support or against.

I can't tell you what amount would cause or, you know, not cause baby -- in baby powder will cause ovarian cancer.

Q. What types of asbestos are associated with ovarian cancer?

A. I haven't done a causal analysis of asbestos and ovarian cancer. I know that the IARC has classified asbestos as a carcinogen, Grade 1, and that also stated that it caused ovarian cancer, but -- about asbestos and fibrous talc, but obviously others will provide more -- more specifics.

Q. Do you have any -- strike that.

Do you have knowledge as to the different

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types of asbestos?

A. No.

Q. What dose of asbestos is associated with ovarian cancer?

A. I have not evaluated the dose of asbestos with ovarian cancer.

Q. What type of ovarian cancer is asbestos associated with?

A. I have not -- as I said earlier, I have not evaluated the specific causal link between asbestos and ovarian cancer. My causal question was, does talcum powder products cause ovarian cancer. And whatever the constituents are, you know, whether they provide evidence in support or against. And, as you said, there may be additional testing.

Q. Does the type of ovarian cancer vary based upon the type of asbestos?

A. Again, I didn't evaluate that -- that body of evidence.

Q. Did you evaluate studies that have explored the potential link between asbestos and ovarian cancer?

A. Yeah. I mean, I didn't, again, evaluate the causal link between that. I looked

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at meta-analysis that, you know, cause, as well as the IARC report that, you know, talks about asbestos and fibrous talc as a carcinogen and also cites studies that show that asbestos causes ovarian cancer. But, again, I wasn't doing a formal causal analysis.

Q. Do you agree that research on the potential relationship between asbestos and ovarian cancer has only considered a small number of cases?

MS. PARFITT: Objection. Form.

A. I mean, ovarian cancer is a rare, rare disease. And, you know, it's going to be a small number of cases, regardless of etiology, what they are trying to study.

Q. How many of the studies involve occupational exposure?

A. I think the predominant --

MS. PARFITT: Objection.

A. -- studies have involved occupational exposure.

Q. How many were nonoccupational, if any?

A. I don't recall the numbers.

Q. Did any of the nonoccupational asbestos studies reach statistical significance?

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MS. PARFITT: Objection. Form.

A. Again, I would have to look at the study that you're talking about. And I just -- I can't recall it off the top of my head.

Q. Can you tell how many women were studied?

A. No, I can't. I mean, you can't ask questions about these things, and tell me how many women. No. You have to show me the study if you want to go down that line of questioning.

Q. I'll show you a study.

A. Sure.

Q. Are you familiar with the Reid study published May 24th of 2011?

A. Yes.

Q. It's one of the studies you looked at; is that right?

A. Yes.

MR. ZELLERS: We'll mark that as Exhibit 30.

(Article entitled "Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-analysis" marked Exhibit 30.)

MS. PARFITT: Thank you.

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THE WITNESS: Can you repeat the question for me?
MR. ZELLERS: Sure.
THE WITNESS: I'm sorry.
BY MR. ZELLERS:
Q. Go to the first page, the right column.
A. Mm-hmm.
Q. Reid. And this article is entitled "Does Exposure to Asbestos Cause Ovarian Cancer?" Is that right?
A. Yes.
Q. The authors state, on the first page, on the right-hand side, right above the No. 1 and No. 2, "Studies that have examined this issue have been limited for two major reasons. No. 1, small number of cases"; is that right?
A. Yes.
Q. The authors state, "Much fewer women than men have been exposed to asbestos, particularly in more heavily exposed occupational settings where relative risks are higher."
You agree with that; correct?
A. Yes.
Q. Then the second major limitation deals with difficulties of diagnosis; is that right?

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A. Yes.
Q. Are you aware of the difficulties that have existed over time in distinguishing between peritoneal mesothelioma and ovarian cancer?
A. Yes. As a general idea of -- you know, because they share histologic similarities.
Q. Did those difficulties affect the reliability of the studies?
A. Yes, but if you look at Table 2 of that report, you see that, despite if you look at studies that review the ovarian pathology, you still see a statistically significant increased risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that -- we still are left with that asbestos causes, you know, ovarian cancer.
Q. The authors of the Reid paper that you reviewed and relied on, Exhibit 30, stated, "It has been particularly difficult to distinguish between peritoneal mesothelioma and ovarian serous carcinoma"; is that right?
MS. PARFITT: Counsel, I'm sorry.

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Where are you pointing to?
MR. ZELLERS: Sure. I'm looking at the --
MS. PARFITT: Thank you.
MR. ZELLERS: -- No. 2.
MS. PARFITT: Uh-huh.
MR. ZELLERS: The last full sentence.
MS. PARFITT: Thank you. I appreciate it.
MR. ZELLERS: On Page -- first page of the article.
MS. PARFITT: Thank you. I appreciate that.
MR. ZELLERS: Sure.
A. Yes.
Q. Have the studies addressed confounding and independent risk factors?
A. Well, again, you know, my examination of asbestos -- I mean, I was not trying to establish a causal link between asbestos and ovarian cancer, you know, when in trying to look at talcum powder products and ovarian cancer, you know, one of the questions was constituents.
And, you know, the IARC agrees that, or at least opines that it is, causally, is a

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carcinogen and lists that and lists the Kamargo study as, you know, that asbestos causes ovarian cancer.
Q. Well, the Camargo 2011 study acknowledges an inability to account for nonoccupational risk factors for ovarian cancer other than age; correct?
A. Again, if I can --
Q. Take a look. Sure.
A. These statements -- it's getting to the end of the day, so...
MR. ZELLERS: Deposition Exhibit 31.
(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.)
BY MR. ZELLERS:
Q. Deposition Exhibit 31 is the Kamargo paper; is that right?
A. Yes.
Q. This is another paper that you have reviewed?
A. Yes.
Q. On the first page, the overview --
A. Yes.
Q. -- it states, "Objective: A recent

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monograph working group of IARC conducted" -- or strike that -- "concluded that there is sufficient evidence for a causal association between exposure to asbestos and ovarian cancer. We performed a meta-analysis to quantitatively evaluate this association."

Is that right?

A. Yes.

Q. If you look at Page 1216, middle column -- are you there?

So I'm looking at the second full paragraph above "conclusion."

"A further limitation of our analysis was its inability to account for nonoccupational risk factors for ovarian cancer other than age."

Do you see that?

A. And what do you mean by that? I mean, I didn't -- again, you know, I --

Q. Let me just ask. Is that a limitation --

A. Yeah.

Q. -- on the analysis?

A. It is a limitation.

Q. Hasn't failure to account for misclassification and known risk factors been

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cited as a reason why causality cannot be established?

MS. PARFITT: Objection.

A. We can't rely on IARC. As you said, one said that it is possibly associated and here, when they haven't arrived at a -- I mean, causality is just not about association in one. I mean, they have to look at other biological mechanisms of asbestos and ovarian cancer, you know, what happens in the lab, what happens -- I haven't done that evaluation.

So, yes, this is a limitation. But this needs to be taken into account with, you know, the entire body of evidence on asbestos and ovarian cancer.

Q. You're looking at and relying on papers, including Reid, Exhibit 30?

A. The IARC monographs.

Q. And Kamargo, Exhibit 31; is that right?

A. Yes. And, again, I'm clarifying that I'm not making a causal determination on IARC, you know. I'm just relying on that, you know, that I'm not -- first of all, I didn't set out to make a causal determination on asbestos and ovarian cancer.

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Q. And you're not making a causal assessment or determination --

A. No.

Q. -- on asbestos; is that right?

A. Yes.

Q. Okay. Under "discussion," Page 1215 --

A. And I'm going to take a break after that whenever you're done. I'm sorry. I need to use the restroom.

Q. That's okay. That's fine. That's fine.

Do you see under "discussion," this is on the left-hand column, second full paragraph, where they're talking about Edelman?

A. Yes.

Q. And the authors state, "They concluded, however, that despite the positive and significant association, there was insufficient information to infer that ovarian cancers were caused by occupational exposure to asbestos because of concerns about tumor misclassification, inappropriate comparison populations and the failure to take into account for known risk factors."

Is that --

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A. Again --

Q. You don't disagree with that, do you?

A. Yeah. I mean, I don't -- but I don't disagree -- I mean, I'm relying on the IARC assessment and others that, you know, there's a causal association between exposure. Again, I did not review. I would have gotten and reviewed evidence, Edelman and White and others, if I had to do it over again.

MR. ZELLERS: Let's take a break. We'll come back and I'll finish up. Thank you.

THE VIDEOGRAPHER: Off the record, 3:32 p.m.

(A recess was taken.)

THE VIDEOGRAPHER: Here begins Media No. 5 in today's deposition of Sonal Singh, MD, M.P.H. Back on the record, 3:43 p.m.

BY MR. ZELLERS:

Q. Dr. Singh, do you agree that exposure to asbestos through perineal cosmetic talc use, assuming the talc contains asbestos fibers, is different than the heavy occupational exposure that's primarily been researched?

MS. PARFITT: Objection to form.

A. Again, you know, I've not professed to

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be an expert in different kinds and routes of asbestos exposure. My -- my sort of -- at least my understanding of my causal question was exposure to talcum powder products and ovarian cancer and whether the constituents can provide evidence in support or refute that association.

So, you know, whether asbestos exposure, what different kinds, others will opine on that.

Q. Do you know what a cleavage fragment is?

A. No. And we can go on on this kind of stuff, and I'll say no.

Q. Do you know how it differs from an asbestos fiber?

A. No. And I'm not a mineralogist.

Q. If I ask you a whole line of questions about different types of asbestos, you're going to defer to other folks?

A. Yes.

Q. Is there any epidemiology substantiating the theory that fragrance ingredients can cause ovarian cancer?

A. I'm not aware of such studies.

Q. Is there any epidemiology substantiating the theory that exposure to trace

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amounts of the heavy metals at issue can cause ovarian cancer?

A. I'm not aware of -- you know, again, I didn't do the evaluation, trace the specific constituents of ovarian cancer. I just was trying to understand the constituents, what are they. I just, you know, whether trace -- trace elements cause inflammation and -- you know, but I am not aware of studies that link them directly to ovarian cancer.

Q. You're not opining in this case that the fragrance chemicals and heavy metals that may be present in baby powder are causally associated with ovarian cancer.

MS. PARFITT: Objection.

Q. Correct?

MS. PARFITT: Form.

A. Yes. I'm not -- again, I'm not opining on the individual constituents of talcum powder products. My opinion is, you know, I look at the exposure and the exposure is talcum powder products, and the presence of constituents, some of which are identified as, you know, Grade 1 carcinogens, others as Grade 2, provide evidence in support, and others may -- you know, others

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may do testing and provide antioxidants and substances which reduce the risk. So that will have to be weighed.

But I am not providing that causal link between the individual constituent and ovarian cancer.

Q. And that would be true for any of the individual fragrance chemicals and heavy metals that may be present in the baby powder; correct?

MS. PARFITT: Objection.

A. I don't have that area of expertise on individual constituents in products.

MR. ZELLERS: I have no further questions. Thank you.

THE WITNESS: Thank you for your time.

(Discussion off the record.)

THE WITNESS: Thank you.

MR. ZELLERS: Thank you, Doctor.

MR. KLATT: Give me a minute to get organized here, Doctor.

THE WITNESS: Sure.

MR. KLATT: Are we off the record?

THE VIDEOGRAPHER: No.

MR. LOCKE: Let's go off the record, then.

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THE VIDEOGRAPHER: Off the record, 3:47 p.m.

(A recess was taken.)

THE VIDEOGRAPHER: Back on the record, 3:51 p.m.

CROSS-EXAMINATION

BY MR. KLATT:

Q. Good afternoon, Dr. Singh. My name is Mike Klatt, and I represent Imerys Talc America in this case.

Have you ever heard of Imerys Talc America before you got involved in this case?

A. I have, but, you know, I don't know in what context and what, you know.

Q. Do you know what Imerys Talc America does?

A. I don't know all the details of the activities or, you know, Imerys.

Q. As you know, Mr. Zellers has covered a fair amount of ground already. And so I'm going to skip around just to ask you some follow-up questions.

You said earlier today, when you were talking to Mr. Zellers, that you potentially intended to write up something about talc and

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ovarian cancer?
A. Sure.
Q. And I just wanted to get a better understanding of what you were referring to.
A. Yeah. So after, sort of -- and I'm not going to do it until this is all over, because I feel that there, you know, I have access to documents that are -- that are sort of protected by court order.
But partly what I'm thinking of is -- like there have been so many systematic reviews and meta-analyses that I was thinking more on the kind of like an umbrella review of all these reviews that I cite in my report and with, you know, some of the rating of reviews.
And then -- and that's sort of my thinking, was that what I would do is synthesize the evidence, that -- what I do best is synthesize the evidence from other studies in trying to -- you know, so it would be separate from, like, because he asked the question, would you do a systematic review? You know, meta-analysis. No. Because there have been so many already.
Q. Have you undertaken that project yet or is this just something you're thinking of?

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A. Yeah. I'm thinking about --
Q. I'm sorry. Let me finish.
This is something you're just thinking about doing in the future?
A. In the future. But I have conceptualized, if I were to do that, that's what I would do.
Q. And if you do do that, you would be obliged, would you not, to disclose to whatever entity, body, journal, that you submitted this work to, that you had been a retained, paid expert by plaintiffs in the talc ovarian cancer litigation; correct?
A. Yeah. And that's been my standard practice. If you go back and look at my papers, you know, my papers on SGLT2 inhibitors, I've disclosed that I was funded by, you know, Janssen. You know, a paper on statins that I wrote last year, I was a paid expert.
So it's just standard practice for us to do that.
Q. And now that you bring that up, there's absolutely nothing wrong with a company like Janssen or any other company hiring an outside expert to advise them and to publish on a certain

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subject; correct?
MS. PARFITT: Objection. Form.
A. I mean, depending -- I don't know the specifics on arrangement, but the question is, you know, as long as the disclosure is transparent, and as long as, you know, the funding mechanisms, what was the reasons, yeah. So it's not like they have commissioned this review.
I mean, first of all, I have just thought about it. I haven't even done it. I'm not sure I'll do it with my time. But you would have to disclose that, yeah.
Q. But my question, and, again, I think we'll go quicker if we just focus on the question asked and the answer to that question.
But my question is: It's entirely appropriate for companies to contact and retain outside experts to advise them and then to publish articles in the literature.
You've done it yourself; correct?
MS. PARFITT: Objection. Form.
You may answer.
A. Yeah. I have actually been, you know, I have worked with Eli Lilly on systematic

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reviews of diabetes medications.
And -- to a point of clarification, I was not paid by them, but I was an expert on that, which is sort of a strange arrangement; right? You don't get paid, but you're still working for. But, you know, that's my area of expertise. So, yeah, companies hire and that's how science works.
Q. And, for example, if you contacted your institution, the University of Massachusetts Medical Center, about this ovarian cancer risk factors web pages that they have, and you had any input on that, you would disclose that you're a paid plaintiffs' expert in talc ovarian cancer litigation; correct?
A. Well, so to do that, I don't know where that web page came from. I didn't contact them. Yes, but, you know, I'm not trying. So I don't know if you're thinking about like the up-to-date example. I didn't want to change. I was just providing them references.
But, yes, if I was trying to make changes to a document that that's on, you know, I'm trying to write something up, then if you look at my letter, it's just a contact point. If I'm trying

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to write something up and say, you know what, it increases the risk of cancer, decreases, then, yes, I'd disclose that.
Q. And just to go over that point --
A. Yeah.
Q. -- when you wrote the editor about Up To Date, suggesting that they update their website regarding talc and ovarian cancer, you did not disclose that, at that time, you were a paid retained plaintiffs' expert; is that correct?
A. Yes. But I asked them to clarify that this was just to update the references, if you look at them.
Q. Now, going back to what this conceptualizing you're having of potentially one day publishing something about talc and ovarian cancer, okay, that's what I'm asking about.
Are we on the same page?
A. Yeah.
Q. Wait. I just want you to know what I'm asking about. Okay?
A. Okay.
Q. Now, you would agree with me, you mentioned this morning there were confidentiality

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orders in place. But you'd admit that all of the case-control epidemiology and all the cohort epidemiology and all the meta-analysis that you've reviewed are all out there in the published literature; correct?
A. The majority of them, studies are, yeah. I mean, Taher is not out in the literature. It's still in somewhere.
Q. There's no -- there's no meta-analysis cohort study or case-control study you're aware of that is controlled or -- by some sort of protective order that would limit you citing it in some sort of review; correct?
MS. PARFITT: Objection. Form.
A. So, first of all, yeah. As you know, Taher is sort of not published. So I don't know how much of the data you can use.
But in terms of protective, I don't know all the rules about what you can use and not use. So, I mean, it's just more my unfamiliarity with the process, but nothing -- if you're asking the question, is something preventing me from doing that? No.
Q. Okay.
A. Can I go ahead and do it? It depends

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on time and other considerations.
Q. And, again, focusing my question very specifically, the case-control studies on talc and ovarian cancer, the cohort studies on talc and ovarian cancer, the meta-analysis on talc and ovarian cancer that you've reviewed in this case and that you've cited in your expert report in this case, none of those are bound by a protective order that would prevent you from reading them, analyzing or publishing on them; correct?
A. None of them are restrictive. Everybody has access. I had, too.
Q. Okay. You talked briefly about the Centers for Disease Control this morning.
A. Yes.
Q. Have you ever worked with them?
A. No. I've applied for grants with them, and I wasn't funded, but I'm aware of them. Yeah.
Q. Have you ever conducted a population-based, case-control study yourself?
A. Yes.
Q. As principal investigator?
A. Yes.

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Q. Have you done so for cohort studies?
A. No. Not a cohort study.
Q. Could we go to Langseth, whatever exhibit number that is?
MR. TISI: I've got it. It's Exhibit 21. I've got a copy of it here.
MS. PARFITT: Yeah. I know.
MR. TISI: Do you mind me giving our copy?
MR. KLATT: No. Not at all.
BY MR. KLATT:
Q. I just have a few more questions. You were already asked about Langseth, but I just have a few more questions for you.
At the time the Langseth study was published, you would agree with me, Doctor --
MS. PARFITT: I'm sorry, Mike. I didn't hear your question. I'm sorry.
Q. Yeah. Let me start over.
MS. PARFITT: I appreciate that.
Q. I'm talking about the Langseth paper that we've marked as Exhibit 21; is that correct? It was published in 2008 by the IARC working group members; correct?
A. Yes. Some of the members. I suspect

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the group is much larger than these folks.
Q. Well, these happened to be epidemiologists on the IARC working group; correct?
A. I don't know all their qualifications.
Q. Do you know any of those people personally who are listed as authors on Exhibit 21?
A. No.
Q. I'll represent to you that they're epidemiologists. You would agree with me, that if you turn over to Page 2, they listed 14 population-based, case-control studies up at the top, and then they had six more hospital-based, case-control studies; correct?
A. Yes.
Q. At this time, there was one cohort study all on the subject of talc and ovarian cancer at the time; correct?
A. Yes.
Q. You would admit that the population-based, case-control studies did not, consistently across the board, show a statistically significant increased risk according to the table in Exhibit 21, the

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Langseth paper. Some were statistically significant, and others were not; correct?
A. Yeah. But I mean, I don't view statistical significance as --
Q. Doctor --
A. -- areas of consistency.
Q. Doctor, I just asked whether they were statistically significant.
A. No. All of them were not statistically significant.
Q. And we're talking about the 14 population-based, case-control studies in the Langseth paper as of 2008; correct?
A. Yes. But I view them as consistent.
Q. And the hospital-based, case-control studies that are on Page 2 of the Langseth paper, the six -- the hospital-based, case-control studies, none of them were statistically significant; correct?
A. Yes. But I still view them as consistent with the overall findings.
Q. And, in fact, when they did a meta-analysis of the hospital-based, case-control studies, that meta-analysis that added all hospital-based, case-control studies together,

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it, in and of itself, was not statistically significant; correct?
MS. PARFITT: Object to the form.
A. Yes. But it was consistent with the overall estimates.
Q. And the cohort study didn't show an increased risk. And the two cohort studies since Langseth have not shown an increased risk of ovarian cancer in talc users; correct?
MS. PARFITT: Objection. Misstates the evidence.
A. I see that, A, two of the cohort studies have showed an excess risk, which is not statistically significant. One study has showed statistically significant increased risk, and the third studies have showed, you know, risk estimates lower than one, but their upper bounds are entirely consistent with what we see here and subsequent to this.
Q. So the population-based, case-control studies collectively show an increased risk. But they're inconsistent; correct?
A. No.
MS. PARFITT: Objection.
A. I mean, let's go to Penninkilampi. I

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mean, they clearly opine that --
Q. I'm asking you about Langseth.
A. Why are we looking at 2008 when we are in 2019?
Q. Because I'm asking the questions.
A. Okay.
Q. You would agree with me that, of the three study designs, cohort studies, hospital-based, case-control studies and population-based, case-control studies, only one of those three study designs shows an overall increased risk of ovarian cancer in talc users; correct?
MS. PARFITT: Objection. Misstates the evidence.
A. No. I mean, at least at that time, you had one, you know, cohort study. I believe that all of them show an excess risk, which is consistent. Two of those study designs that you're talking about, the hospital based and the cohort, did not show a statistically significant, which I still believe a significant excess that's consistent.
Q. And you said earlier that you consider and use the Bradford Hill considerations;

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correct?
A. Sorry. Just give me a second.
Yeah. The Bradford Hill overviews as one.
Q. And you know, Sir Bradford Hill himself said that, in evaluating consistency, you have to look at consistency across different study designs; correct?
A. Yeah. And times and places and other things.
Q. But I'm correct that Dr. Bradford or Sir Bradford Hill said that you have to look at consistency across different study designs; correct?
A. That's what I state in my testimony, as well in my report cites that specific phrase, consistency across study designs, times and places. So I am not -- you know, I am, in fact, quoting him when I cite that.
Q. You said, on Page 15 of your report, that, "Talc-based body powders are used habitually for months or years rather than just a single application"; correct?
A. Where is that?
MS. PARFITT: Page 15.
Q. Page 15.

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A. Where is that? I'm sorry. Which part of it? 15. I know I have 15. Is it the last paragraph or --
MS. PARFITT: Yeah.
A. I don't see -- okay. Yeah.
Q. And what did counsel just point out to you?
A. Yeah. I saw that. That's correct.
Q. And can you read what you said there?
A. "Talcum powder products are used habitually for months or years rather than a single application or single body."
Q. Would you flip over to Page 54 of your report, please. In Paragraph 6 there, you say, in the third sentence that, "Recall bias is less likely to occur for chronic daily exposures such as talc"; correct?
A. That's, you know, that's my understanding.
Q. Talc, in your estimation, is a chronic daily exposure; correct?
A. That's how -- that's my understanding that, you know, women are using it.
Q. You, in response to Mr. Zellers' questions earlier today, said that one of the

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things you had reviewed was an Exhibit 47 to Imerys employee Julie Pier's deposition.
Do you recall that?
A. Yes. If you can show me that.
MR. KLATT: Sure.
THE WITNESS: Thank you.
MR. KLATT: I'm sorry. I'm sorry.
THE WITNESS: Exhibit --
MR. KLATT: Yeah. Let's mark it as the next exhibit. And that would be 33; is that correct?
MS. PARFITT: 32.
COURT REPORTER: Here is 32 that you haven't used.
MR. KLATT: Let me do this. Yes. That will be 32.
(Chart marked Exhibit 32.)
MR. TISI: The chart?
MR. KLATT: Yes.
BY MR. KLATT:
Q. I'm going to show you what's been marked as Exhibit 32 to this deposition. But for future record references, it also has, in the upper right-hand corner, a photocopy, Exhibit No. 47; correct?

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A. Yeah.
Q. Exhibit 47 was the exhibit number at Ms. Pier's deposition, and Exhibit 32 is the exhibit number we're marking this today; correct?
A. Okay.
Q. Would you agree with me that you don't have the expertise or knowledge to tell me that any of the samples on Exhibit 32 to today's deposition show asbestos in Imerys talc that ended up in Johnson & Johnson's baby powder, do you?
MS. PARFITT: Objection.
A. I mean, it says, you know, anthophyllite -- yeah. I mean, I don't have asbestos expertise here.
Q. Let's -- you understand that most of these samples, the source of these samples isn't even identified?
MS. PARFITT: Objection. Form.
A. Yeah. But -- but, actually, can I answer that?
So, for example, separate from the source, I mean, I understand that it says chrysotile asbestos for the first one. It says serpentine. It says chrysotile.

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Q. And where on that first one, and we're looking at the very first line across the top of Exhibit 32 --
A. Sure.
Q. -- where in the world does it say that that was a sample of talc that ended up in Johnson & Johnson's talc-based body powder products?
A. Well, my understanding, and I can share that, that this was -- this was that -- that testimony was given that this was a testing of mines that was being mined by Imerys or -- I mean, that contained asbestos.
Whether it ended up in baby powder was not the question. The question was: Does talc contain asbestos?
Q. Did plaintiffs' counsel ask you to make that assumption?
A. No. No.
Q. Okay. Well, then, I'm confused, because Imerys and its predecessors have tested literally thousands of samples of talc from competitors, from their own mines, from mines that are never used for cosmetic purposes or baby powder, so how can you tell me that the first

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sample on Exhibit 32 has anything to do with baby powder?
A. Well, I'm not telling you anything to do with baby powder. My question is that, you know -- that what constitutes talcum powder products. And based on this and, you know, talc is mined together with all these other particles, I wanted to know, what are the results.
And at least based on my understanding of these results, again, I'm not a mineralogist, they can argue whether the amount of asbestos is significant or, you know, these fibers, chromium, cobalt, nickel are significant. My understanding is that these particles are present.
Q. Can you tell me, based on your own knowledge or expertise, that any sample listed on Exhibit 32 was from talc that ended up in Johnson & Johnson's baby powder or Shower to Shower talcum powder products?
A. No. I cannot.
Q. Okay. You referred in your report to the Shukla paper; correct?
Do you recall that?
A. Show it to me. It's been a while.
Q. Sure. I'm going to give you the page

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on your report where I think you refer to it.
A. I know it's in the biologic plausibility section somewhere.
Q. Look on page -- I believe it's Page 61 of your report.
A. Yes.
Q. No. I'm sorry. It's Page 59 of your report. And it's the third paragraph down.
A. Mm-hmm.
Q. And you say, in the middle of the third paragraph, "In studies of human mesothelial cells, both nonfibrous talc and asbestos have shown evidence of genotoxicity," and the reference is 109, and my understanding is reference 109 is the Shukla paper published in 2009; correct?
A. Where are you referring? I'm sorry. In Page 59?
Q. Page 59 of your report, third paragraph.
A. Yeah.
Q. Second sentence.
A. Yeah. It says here, should be Shukla. Yeah.
Q. Did you read the Shukla paper?

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A. I read -- you know, I didn't read it line by line. But, yes, I read it.
Q. You know the Shukla paper has nothing to do with genotoxicity; correct?
A. I mean, we can look at it.
Q. Sure. It's about gene expression; correct?
MS. PARFITT: Let's take a moment, Mr. Klatt, see if he can look at the study here.
Q. Do you have it handy, Doctor?
A. No. I don't.
MS. PARFITT: What is he referencing, 109?
A. Shukla. I mean, it might be in my files.
Q. Well, I apologize. I thought I brought an extra copy, but I don't think I have one with me.
(Discussion off the record.)
Q. Well, just look at the title. The title is "Alterations in Gene Expression in Human Mesothelial Cells Correlates with Neural Pathogenicity." Correct?
A. Yes. I remember that title and abstract. Yes.

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Q. Gene expression is something that occurs in our bodies every day; correct? Trillions of times every day; correct?
A. Yeah. Yeah.
Q. And changes in gene expression, in and of themselves, don't establish genotoxicity; correct?
A. Yeah. And I'm not -- again, this, you know, in the section on biologic plausibility, I'm not making this argument that talc is an established mutagen and, you know, whether it's a genotoxic or nongenotoxic carcinogen. I'm just citing the studies.
So, I mean, again, I don't have that expertise, and, you know, does it provide evidence for or against biological plausibility mechanisms.
Q. Okay. But you don't have the expertise to judge that; correct?
MS. PARFITT: Objection.
A. No. I have expertise to judge whether these studies suggest evidence of, you know, changes and we should probably just look at it -- give me a second.
Q. Sure.

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MS. PARFITT: Give me a second.
Q. My specific question is you cited Shukla for evidence of genotoxicity, but it says nothing whatsoever about genotoxicity, does it?
A. We have to look at the paper before we say that.
It's 109. Yeah. Let me look in my binder. I think I have all the studies.
Q. Doctor, I'll represent to you, in the interest of time, I've searched the Shukla paper, and the word "genotoxicity" or "mutagenicity" is never mentioned in the paper.
A. I -- I don't want to deny that. It may be. I just feel that I wouldn't have used that term had I not seen it there.
Q. In the interest of time, rather than wasting time, let's move on.
You'd agree with me that pelvic inflammatory disease is chronic inflammation of the ovaries, fallopian tubes and peritoneum; correct?
A. Yes.
Q. And, yet, you cited the Rasmussin paper, and the Rasmussin paper says that high-grade serous ovarian cancer, which is the most common form of ovarian cancer and the most

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common in these lawsuits, wasn't associated with pelvic inflammatory disease; correct?
A. Again, I don't remember the papers. Sorry.
Q. All right. Well, it's on Page 58 of your report and it's reference 122.
A. Which page of my report?
Q. Page 58 of your report that cites reference 122.
MS. PARFITT: Here's the article.
Q. Do you see the reference?
A. Yeah. Yeah.
Q. Do you see the reference in your report?
A. Sure.
Q. And reference 122 is to the Rasmussin paper from 2017 on pelvic inflammatory disease and ovarian cancer; correct?
A. Yeah. And my citation is correct. I mean, about borderline ovarian. I don't misquote the study.
Q. I didn't say you misquoted it, but the study does stand for the proposition that the most common form of ovarian cancer, both in the U.S. and in these lawsuits, high-grade serous

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ovarian cancer is not associated with pelvic inflammatory disease; correct?
A. Where does it show that? I didn't --
Q. Can you go to the "Discussion" section.
A. Again, you know, my view of inflammation was, you know, I was looking for evidence for or against. And, you know, I wasn't disaggregating by ovarian cancer subtype, but I'm happy to look at it.
MS. PARFITT: Mark, do you have a page in the article?
MR. KLATT: I don't know if we have the same pagination, but my page is --
MS. PARFITT: Here. I got it. It's 29 of 33.
MR. KLATT: I believe that's right.
MS. PARFITT: Okay.
MR. KLATT: It's the "Discussion" section.
MS. PARFITT: Yes.
BY MR. KLATT:
Q. And if you look at the "Discussion" section, Doctor --
A. Yes.
Q. -- it starts -- the very first

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paragraph starts with "to our knowledge"; correct?
A. Yeah.
Q. Okay. Go down one, two, three, to the fourth paragraph starting with "in the present study"?
A. Sure.
Q. And in that paragraph, tell me if I correctly quote this sentence.
"Conversely, no convincing associations between PID," which is pelvic inflammatory disease, "and the risk of high-grade serous, mucinous, clear cell or endometrioid ovarian cancer were noted in the main analysis."
Did I read that correctly?
A. Yes.
Q. And then if you go down to the very next paragraph that begins with "nevertheless."
A. Yeah. I see that, but I --
Q. Wait. Wait.
A. No. No. I need to answer your question.
Q. I'm just asking you, first of all, if I'm reading this correctly.
A. Sure.

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Q. In the next paragraph that begins with "nevertheless," do you see what I'm talking about?
A. Yeah.
Q. There's a sentence that says, midparagraph, "In contrast, no associations between pelvic inflammatory disease and high-grade serous ovarian cancer were observed"; correct?
Did I read that correctly?
A. Our results suggest -- I'm sorry. Where --
Q. In contrast. Do you see the sentence that says "in contrast"?
A. Where was it? Is it in the same paragraph?
Q. It's the paragraph starting with "nevertheless, our results."
A. Yeah. But it says differentially. Where does it say in contrast? In contrast. Yeah.
Q. Okay. Can you read that sentence?
A. "In contrast, no associations between PID and high-grade serous ovarian cancers were observed."

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Q. So the paper you cited, the 2017 Rasmussin paper on pelvic inflammatory disease and ovarian cancer is inconsistent with the theory that chronic inflammation causes high-grade serous ovarian cancer; correct?
A. Let's go to Paragraph 3.
Q. Could you just answer my question?
A. Yeah. I'm trying to.
MS. PARFITT: Objection.
A. No. It isn't inconsistent.
Because if you look at Paragraph 3, they state, "Furthermore, we observed similarly increased risks of serous and mucinous borderline tumors associated with PID status. Furthermore," and they also state, "Sensitivity analysis revealed statistically significant increased risk of low-grade serous and endometrial when using data from the North American..."
So I don't think your -- and concerning the histologic subtypes, indications of risk of low-grade serous cancers were noted in the main analysis. I wasn't disaggregating. But this entirely consistent with what I quote here, that you increase serous type and you increase low-grade type and you increase histologic.

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You are trying to disaggregate this into a high-grade serous. I don't know what's in the lawsuit. I'm really not opining on --
Q. I'm not trying to disaggregate anything, Doctor. I'm saying Rasmussin, the study that you --
A. Yeah.
Q. The study that you chose to cite --
A. Sure.
Q. -- in your article indicates there's no association between pelvic inflammatory disease that is a chronic disease of the female reproductive tract and high-grade serous ovarian cancer; correct?
A. And the same --
MS. PARFITT: Objection is.
A. -- study showed an increase risk of --
Q. Is that correct?
MS. PARFITT: Let him finish, please.
A. -- between PID and serous ovarian cancer. So it sort of is -- is consistent with my hypothesis of inflammation and ovarian cancer.
I was not disaggregating histologic subtypes.
Q. My question is not about low-grade

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serous that doesn't occur very often. My question is about high-grade serous ovarian cancer in the evidence from the Rasmussin paper, and they say clearly twice, that pelvic inflammatory disease is not associated with high-grade serous ovarian cancer; is that correct?

A. That's what they state in the study. But they also state clearly that serous ovarian cancer is associated with PID status. So that's also clearly stated.

Q. And if, indeed, as they state, there is no association between high-grade serous ovarian cancer and pelvic inflammatory disease, that's inconsistent with the theory that inflammation causes high-grade serous ovarian cancer; correct?

MS. PARFITT: Objection. Form.

A. So, again, you know, first of all, you know, I -- other people will opine to the biologic sort of arguments about inflammation and ovarian cancer. And I did not disaggregate specific, and I don't think this study is inconsistent with what I state here. And I note that borderline ovarian cancer.

So this is entirely consistent with the

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inflammation hypothesis. And I just, you know --

Q. In your report, you cited what you thought was consistent with the inflammation theory, but you didn't cite the evidence from Rasmussin that was inconsistent with the inflammation theory; correct?

MS. PARFITT: Objection.

A. No. I was not disaggregating to the level of each histologic subtype.

Q. Well, didn't -- in your report, on Page 58 --

A. Yeah.

Q. -- didn't you make the specific point that Rasmussin said inflammation was associated with low-grade cancer?

A. No. It just said increased risk of borderline ovarian cancer.

Q. Okay. Borderline. That's a specific type of ovarian cancer.

A. Sure.

Q. So you did disaggregate in your report, didn't you?

A. Sure. Yeah, but I mean, if you look at the study, and we want to disaggregate it, the study still shows a risk of serous ovarian

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cancer. So if we disaggregate it, then we have to disaggregate the way they have defined it.

Q. And when we disaggregate, you come to the conclusion that inflammation is associated with borderline ovarian cancer. But, in fairness, you have to come to the conclusion that inflammation is not associated with high-grade serous ovarian cancer?

MS. PARFITT: Objection.

Q. If you're being objective; correct?

MS. PARFITT: Objection. Misstates testimony.

A. I am being objective. I am providing that they conclude, not I conclude, that, you know, inflammation is PID, you know, it's just one aspect of inflammation. PID is associated with serous ovarian cancer. And, yes, it is not associated with high-grade epithelial ovarian cancer.

Q. You talked with Mr. Zellers earlier today about recall bias, correct, and how it can operate in case-control studies?

A. I don't recall the details.

Q. But you recall the subject was discussed --

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A. Yes.

Q. -- correct?

A. Yes. And I'm going to take a break in a minute.

Q. Sure. Do you know if, in any of these case-control studies -- well, let me back up.

A case-control study takes a group of cases which are women with -- who already have ovarian cancer, and interviews them; correct?

A. Yes.

Q. And then it takes a group of controls and, in the context of a population-based case-control study, those controls are healthy women out in the community; correct?

A. Yeah. In the context of -- yes.

Q. Do you know if any of these case-control studies, when they were interviewing the case women who had ovarian cancer, asked them when they entered the study, "Do you have any preconceived notions about what might have caused your ovarian cancer?"

A. I didn't review that specific question.

Q. Wouldn't that be an important question to ask? Because if a woman already has a preconceived notion from research or word of

mouth what might cause her ovarian cancer, that may bias the results; correct?
MS. PARFITT: Objection.
A. There's lots of different questions you could ask them. You know, I would have, if I had designed a study, I would have asked many other questions.
Q. And would you have asked that one, "Do you have preconceived notions as to what might have caused your ovarian cancer," before you entered the study?
A. I don't -- you know, I don't -- I haven't thought about that conceptual or new study. I'm not sure that is that important question to ask.
Q. It wouldn't be an important question to ask women entering a study, a case-control study --
A. Sure.
Q. -- women who have ovarian cancer, "Do you have a preconceived notion about what caused your ovarian cancer?"
A. You know, I've done -- designed case-control studies of etiology cases and outcomes. I've never asked the participants

about what is your preconceived notions about certain outcomes.
I mean, I'm just trying to understand, why would you ask that, because --
Q. Because you're trying to eliminate bias from the study; correct?
A. Yeah.
Q. And if you enter the study with a preconceived notion what caused your ovarian cancer, you already have a bias; correct?
MS. PARFITT: Objection.
A. But I mean, aren't you introducing bias by asking these questions? "Okay, what is your preconceived notion?" I'm trying to understand this question. I just don't think that --
Q. So it's your testimony that, typically, in these case-control studies, the women who have the disease of interest, in this case, ovarian cancer, are not asked, when they enter the study, if they already have preconceived notions about what caused their ovarian cancer?
A. Yeah. In my opinion, if I were to design a next case and control study, I'm not sure that would be a question. I would have to think about why I would ask that question to

eliminate for the possibility of recall bias. Others may design it differently.
THE WITNESS: I'm going to take a break.
MR. KLATT: Sure.
THE VIDEOGRAPHER: Off the record, 4:30 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Back on the record. 4:36 p.m.
BY MR. KLATT:
Q. Doctor, are you board certified in epidemiology?
A. No.
Q. Are you a member of the American College of Epidemiology?
A. No.
Q. Are you a member of the Society for Epidemiologic Research?
A. No.
MR. KLATT: All right. I'm going to turn it over to Mr. Locke. Thank you for your time.
THE WITNESS: Thank you.
THE VIDEOGRAPHER: Off the record,

4:36 p.m.
(A recess was taken.)
THE VIDEOGRAPHER: Back on the record, 4:38 p.m.
CROSS-EXAMINATION
BY MR. LOCKE:
Q. Doctor, my name is Tom Locke. I represent the Personal Care Products Council.
Prior to this litigation, had you ever heard of the Personal Care Products Council?
A. No.
Q. Sometimes it goes by the name of PCPC. Have you ever heard of that?
A. No.
Q. Previously, the Personal Care Products Council was known as the Cosmetics, Toiletries and Fragrances Association.
Prior to this litigation, had you heard of that entity?
A. No.
Q. And sometimes that's abbreviated, CTFA. Had you heard of that entity?
A. No.
Q. Have you, prior to this talc multi-district litigation that we're here on

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today, have you worked with any of the plaintiffs' lawyers with whom you've had dealings in talc?

A. Yeah. I mentioned that I worked with Attorney Restaino in the atorvastatin that is listed on my testimony.

Q. Anyone else?

A. No.

Q. Have you worked with the Beasley Allen firm?

A. They're not -- I don't know if they're part of this talc. The name sounds familiar. I just don't know the name of the lawyers.

Q. Right. They're part of the lead plaintiffs' counsel in this multi-district litigation.

A. But I just have had correspondence with these lawyers. So, you know, I may have had -- received, I don't know, documents or -- I don't know if invoices or something that may have. But I don't -- I haven't, like, corresponded with the lawyers of Beasley Allen.

Q. What I'm asking about is whether you had worked with the Beasley Allen firm prior to this talc litigation.

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A. I have listed the -- you know, listed the cases I worked for. I don't remember the name of the counsels and, you know, who were on the firms. So if it ended up that they were involved in Viagra or something else, that's just a recollection issue.

Q. Okay. Mr. Klatt asked you about materials authored by defense experts. Let me elaborate on that a little bit.

Are you aware that various defense experts authored reports in connection with prior talc litigation?

A. No. I'm not aware.

Q. Are you aware that there were prior talc trials?

A. I mean, I have seen it in the news that -- I don't know if they're in state court, federal court, you know. I see it in the news.

Q. Did you --

A. California or something. Yeah. I'm not aware.

Q. Did you ask for the testimony of any defense experts who may have testified regarding epidemiology in connection with that other talc litigation trials?

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A. I remember asking about this specific trial. I have not asked for other trial testimony, I don't think.

Q. When you say "this specific trial," what do you mean?

A. When I said -- you know, I said, in this litigation, have epidemiology testimony been submitted. And I have asked for it. Yeah.

Q. Would it be relevant to you that other scientists have analyzed the very same issues that are encompassed in your report and testified on behalf of defendants in other talc litigation?

A. Yeah. And as you see that, I have not even had a chance to review the expert report of -- on behalf of the plaintiffs that were submitted in the list.

So, yes, it will be nice to do that. A, how much time; and, B, you know, I think it would probably be more prudent to wait for the epidemiologists on this particular case.

But, you know, as you said, I haven't even had the chance to review the plaintiffs' experts. And, you know, I asked for defendants' expert, you know, report.

Q. You asked for defendants' expert

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reports in this litigation.

A. Sure.

Q. But you didn't ask for defendants' expert reports, deposition transcripts or trial testimony in the prior talc litigation?

A. How do I know? I mean, I'm not very familiar with how these, you know, different trials are occurring, what you can share, which attorneys are involved in which trials.

I'm sorry. I didn't ask for it. I know that, but I'm just not familiar with that process, what they can share.

Q. Okay. Can you go to Page 10 of your report. And I guess there are two exhibits to it, or it's referred to in two exhibits.

Are you looking at Exhibit 10 there?

A. Exhibit 10.

Q. On the front page.

MS. PARFITT: It's your report. Yes.

A. Exhibit 10. Yes.

Q. So if you could go to Page 10, I'd appreciate that. And on Page 10, you're discussing, among other things, the advantages and disadvantages of cohort and case-control studies; is that correct?

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A. Yes.
Q. Okay. If you would look at the paragraph that begins with the phrase "case-control studies."
Do you see that there?
A. Yeah.
Q. Okay. You're explaining your opinion why case-control studies have some advantages over cohort studies in that paragraph; is that correct?
A. No. Not necessarily. I mean, that just talks about the strength and weaknesses of various studies designs. I mean, in fact, you know, it talks about whether, you know, that, in fact, it says exposure is ascertained retrospectively.
So I'm just talking about the strength and limitations of various designs.
Q. Okay. I was using advantages and disadvantages.
Is there a significant difference between those two?
A. That's just the term we use. Yeah.
Q. Okay. Now, one of the strengths, in your opinion, of a case-control study, is that it

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captures the entire time period when an ovarian cancer illness could occur; is that correct?
A. That's not necessarily like an entire time. First of all, we don't know the precise number of years.
But, yes, we know that it is a long-term exposure. So case-control studies allow us to ascertain long-term exposure. So that's a much more accurate reflection.
Q. And you were saying one of the weaknesses of a cohort study is that it might not capture all of the ovarian cancer cases because ovarian cancer can develop over a long period of time; is that correct?
A. Yes. After a particular agent, if it's related, you know.
Q. Okay. And you mentioned, in fact, there's a sentence here, "It is important to determine the latency and induction between the exposure and the disease to assess the duration of follow-up"; is that correct?
A. It is.
Q. Okay. And then you give the example of smoking. And you talked about, if you looked at it for a 12-month follow-up study, that would not

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be useful, because you couldn't find all of the lung cancer cases.
A. Yes. And that sort of applies to Gonzalez. And it was a six-month study, and some of the other cohort studies that were of limited duration.
So, yes, I mean, I don't know about the time course exactly of lung cancer risk, but can apply to various outcomes.
Q. Okay. So what is the latency period for perineal talc exposure and ovarian cancer?
A. I do not have -- I don't know, because, you know, I don't -- again, I don't elucidate the mechanism of ovarian cancer and the precise link. So I cannot tell you that X number of days after perineal talc or months after. I know that it is long-term. It could be months to years. And that's as much as I can say.
Q. So your example, when you were talking about 12 months, actually, that really wouldn't be a problem or we don't know whether that's a problem or not because it could be months?
A. No.
MS. PARFITT: Objection.
THE WITNESS: Sorry.

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A. So, yeah, months would be a problem. It's mostly -- I mean, yes, we have some bounds, but most of the studies we see, it is likely to have been, you know, several years after exposure.
Q. And how do you know that? Which studies have you reviewed or analyzed that say that it's several years after exposure?
A. Well, all of -- you know, the case-control studies that have provided data on duration of exposure and show evidence of duration responsiveness suggest that -- so, for example, Penninkilampi and others suggest that this is -- you know, while there are increased risks before both more than 20 years or more than 3,600 applications as well as those are less, the risk is higher among those with higher duration.
But, again, I cannot partition this at 20 or 15.
Q. Okay. You have a phrase in here that says "because ovarian cancer develops over many years."
Is that an accurate assessment of your views?
A. Where is that?

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Q. If you look at the next paragraph, first sentence, last clause.
A. Yeah.
Q. Other plaintiffs' experts have stated in their reports that the latency period could be decades.
Would you disagree with that?
A. Yeah. I mean, when I say many years, it could be -- yeah, I just --
Q. You don't know?
A. I don't know the precise. I don't want to quantify the number of years.
Q. Okay. I want to shift topics a little bit here. You reference Linda Loretz's deposition transcript in -- I think once in your report.
If you would go to Page 7, I believe it is. It's in a footnote. Footnote 1.
A. Mm-hmm.
Q. Now, did you read the entirety of Dr. Loretz's deposition transcript?
A. Again, these are so many documents. I mean, I reviewed, you know, not -- but I don't know if I read the whole transcript. Yeah.
Q. Do you know how many days she was

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deposed?
A. I don't recall.
Q. More than one day?
A. I don't know that. I'm sorry.
Q. So her deposition transcript, I'll represent to you, is 1,133 pages in length.
Did you read all that?
A. No. I didn't agree that I read all of them either. Yeah.
Q. Okay. I was a little confused because I thought you had said, for hers, that you had read the whole thing.
A. No. I didn't say I had read -- you know, I have read the transcript, but it doesn't mean that I read every, you know, precise word and precise --
Q. Do you know what her background is?
A. No, I don't.
Q. Do you know if she's a scientist?
A. I don't remember, you know, the specifics of the transcript.
Q. How is it that you picked out this quote then on -- that's Footnote 1 or this citation, Footnote 1, Page 7?
A. Yeah. I mean, it's not even -- that's

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not even a citation. I mean, it's -- I feel that, and we were discussing that, you know, could a randomized trial be here conducted. And to my mind, it would be unethical. So...
Q. Well, yeah. But then you say, "Defendants here have admitted this fact."
And so I'm just wondering what brought you to that particular part midway in her deposition, the second day of her deposition of a three-day deposition.
A. Some of this has, you know -- it just doesn't -- I don't know why I would, you know, put it -- but it's sort of -- it's even irrelevant if you take her out of it. Because, you know, it's like, are we really going to do a randomized trial?
Q. I agree with you. It's irrelevant.
A. Yeah.
Q. If you could go to Page 62 of your report. You've got a caption there "Cosmetic Expert Review Panel Report."
Do you see that?
A. Yes.
Q. Roman numeral XII?
A. Yes.

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Q. Do you know what the name of the organization is that you're referring to in that paragraph?
A. I don't know the name.
Q. Do you know if Dr. Loretz testified regarding that review?
A. If I have cited her, then I have.
Q. Well, you didn't cite her on this portion. That's why I'm asking about it.
A. I don't know. I mean, you're asking all these different names. They're all -- if I haven't cited her, then I haven't reviewed it.
Q. Okay. Have you heard of the Cosmetic Ingredient Review?
A. Yes.
Q. Sometimes referred to as CIR?
A. Yes.
Q. Dr. Loretz, in her deposition, references the CIR dozens of times, doesn't she?
A. Again, as I said, I didn't review the entirety of the thousand pages.
Q. Okay. I'm just trying to understand what you did review and you didn't. You wrote a paragraph about the CIR. And I'm trying to understand why you didn't reference Dr. Loretz

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when she testified about that.
A. So, as you can see, it's reference to the published report, and, you know, I reviewed -- again, even that was lengthy document, and, you know, I wanted to review that for completeness and understand that.
Q. Did you read the entirety of that report?
A. As much as I can. Not every word in every sentence.
Q. Okay. Do you know if the FDA plays a role in the CIR's review that you're referring to on Page 62 of your report?
A. I'm not aware of the specific composition, but I know that FDA is -- attends or is a member or has some sort of role there.
Q. Do you know who the Consumer Federation of America is?
A. No.
Q. Do you know if they play any role in the CIR report?
A. I don't know. And maybe it's in the study and I can't tell you offhand who is in this panel.
Q. It's also in Dr. Loretz's deposition.

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That's the reason I'm exploring it.
Do you know that one of the missions of the Consumer Federation of America is to represent consumers in connection with Cosmetic Ingredient Reviews?
A. I'm not aware of that.
Q. Okay. Do you know who was on the panel of the CIR review?
A. No.
Q. Do you know whether there were toxicologists who were part of the panel?
A. I don't know that.
Q. You criticize the panel makeup because it was "primarily composed of dermatologists."
A. Sure.
Q. Do you see that?
A. Yes.
Q. Do you know why dermatologists would be relevant to a review of cosmetics?
A. Yes. I mean, yeah. But, of course, the majority of cosmetics are on -- you know, applied on the skin. Yeah. It would be relevant.
Q. So they would be relevant to a CIR review?

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A. Yes.
MS. PARFITT: Objection.
A. But specific to talc, you would want more diverse representation with gynecologists, oncologists, epidemiologists.
So it's not that it was a criticism of the CIR review panel or whoever was on that as a dermatologist, but specific to it, did they have the expertise to -- and maybe they did, but I'm just pointing that out.
Q. So you don't know, one way or another, whether they had the expertise?
A. Yeah. I mean, from my understanding, they didn't have expertise in carcinogenicity and epidemiology.
Q. What do you base that on?
A. Yeah. I mean, you know, some of the names that are here, they were dermatologists. That's sort of my understanding.
Q. Did you look them up and investigate what they do or what they have done in their careers?
A. No. I have not.
Q. Okay. So you're criticizing them as not having the capability of doing the review,

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but you don't really know their expertise?
MS. PARFITT: Objection. Misstates his testimony.
A. Yeah. It doesn't say -- first of all, it's not a criticism. It just says, what is the composition of the panel. It says it was composed of, you know, expertise in epidemiology and carcinogen -- so it's just sometimes panels -- and it may have been very appropriate for the 100 and whatever products that were evaluated by that panel.
Q. Okay. One of the things that you say --
A. Sure.
Q. -- is that there was a -- the review was limited or limited its assessment to animal and clinical studies on talc that did not contain asbestos.
Do you see that?
A. Yeah.
Q. You would agree that the CIR reviewed all of the epidemiological studies that were available at that time; correct?
MS. PARFITT: Objection. Misstates testimony.

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A. I don't know -- you know, I know that they reviewed the process and they looked at studies, and I don't know if it was all epidemiologic studies, but I think and I understand that presumption was that talc does not contain asbestos. I mean, that's what -- the premise they started out with.

Q. Well, did the epidemiologic studies make a distinction between talc and its constituents or alleged constituents?

A. Yeah. I mean, there are -- as I cite in my report, there are -- they don't make distinctions, but they -- some of the studies -- you know, some of the testimony we've discussed, some of the, you know, testing we've discussed, and some, you know, small publications suggest that talc may contain asbestos. So you have these evidence.

But the CIR review was already carried out with the presumption that talc did not contain asbestos.

Q. But they reviewed all of those studies that you referenced, or do you not know what they reviewed?

MS. PARFITT: Objection.

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A. I mean, I do not know every study they reviewed. I'm just providing -- I don't know every study that IARC reviewed.

Q. Well, you could find that out by looking at the studies; right?

A. There's not enough time. There's so many studies in this and so many reports, so many assessments that --

Q. But you're criticizing the CIR.

A. Yeah.

Q. And saying it limited its assessment.

A. Sure.

Q. And I just want to understand the basis for that statement, and what you're saying, testifying here today is you don't know what the CIR reviewed.

MS. PARFITT: Objection. Misstates testimony.

A. No. That, and we can look at it. Let's look at the, you know, the --

Q. But you made the statement.

A. Sure.

Q. And I'm asking you, sitting here today, can you say what they reviewed?

A. Yes. I know they reviewed -- because

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they asked -- this statement is about the question they asked. They asked the question, that talc fiber not containing asbestos, does it cause.

So if they ask the question already, we know that, they presume there was no presence of. So it's about the question that I'm stating it.

Q. But the epidemiologic studies, when they're analyzing talc use among women, they're not making a distinction between talc that contains or doesn't contain constituents. They're talking about women who use products; correct?

A. That is correct.

Q. So if your theory is correct and talc contains harmful substances in addition to talc, then the epidemiologic studies would have reviewed women's exposure to those constituents; correct?

A. Yeah. So, I mean -- so if you look at what I've written, the review was carried out under the flawed assumption that cosmetic grade, you know, talc was -- did not contain that. And also limited to talc that did not contain. And also concluded that there was no evidence of talc

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migration.

I do not say that, you know, there was no -- they did not review the -- the epidemiologic studies of talcum powder products. That's not -- you know, they reviewed it. But I'm just pointing out the limitations of that.

Q. Didn't CIR cite the very same studies that were available as of 2013 that you cite in your report?

A. Yes.

MS. PARFITT: Objection. Form.

A. Again, you know, I don't know if they cite evidence of biologic plausibility. I don't know if they cite evidence of talc migration. I don't know how they interpreted the evidence of -- just because they cited a study does not mean that they interpreted the data in the same way that I did.

So I don't know what studies specifically in each section they cited.

Q. Okay. One of the things that you say, "as a result of these serious methodological shortcomings and funding biases." Let me ask you about that.

A. Sure.

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Q. Is a review that's funded by an entity with an interest in the outcome of that review inherently flawed?

A. No. It isn't. And this is just, you know, one of -- and, you know, it's a potential. It should be potential for funding biases. It doesn't mean that just because it was funded by PCPC or CIR, it is, you know, biased.

But yes, I mean, so, for example, my report and testimony, because it's funded by, you know, should be examined for potential biases. Just like, you know, CIR's report should be.

Q. I want to ask you about the timing of things, because sometimes you have referred to reports that were done a while ago. And in this case, you do that with CIR. You say, "The findings of this panel have been superseded by several new epidemiologic studies," and so forth. The line goes on.

Is it your opinion that -- well, let me ask this way: At what point in time can we say that the epidemiologic studies have sort of been completed so you could rely on that information?

MS. PARFITT: Objection. Form.

A. Yeah. I mean, so you rely on

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information from, what, 1982, Cramer one. But I guess the question is -- I don't know, I'm not trying to put questions in your mouth. But I don't -- I can't -- because I evaluated the causal question as of 2017 and didn't arrive at an opinion until late 2018.

I did not go year by year and, say, okay, in 2005, when IARC looked at this, could we have concluded, possible, a problem? In 2010, when Langseth looked, or 2015.

So I did not segmentate it by time. And you're just asking, even by epidemiologic study. It doesn't work. You have to look at the whole body of evidence and come to a conclusion.

Q. Isn't it true that, prior to the talc litigation, no scientist had published an article stating that talc causes ovarian cancer?

MS. PARFITT: Objection to form.

A. Yeah. I mean, you know, I think a lot of these articles have talked about -- and scientists don't necessarily publish statements about causation, you know.

You have seen that Health Canada has clearly stated that talc causes ovarian cancer. Yes, so, in fact, not even scientists, but now we have

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regulatory agency in late 2018. So things take time. And, you know, people, scientists take time to come to conclusions.

Q. Okay. Let's go to Exhibit 22.

A. Which is?

Q. That's the Berge -- I believe that's how it's pronounced -- report?

MS. PARFITT: The Berge study?

MR. LOCKE: Yes, yes. I'm sorry.

BY MR. LOCKE:

Q. So if you could turn to Page 9, can you read the last sentence right before acknowledgments, beginning with the word "several." If you could read it out loud, please.

A. "Several aspects of our own results, including the heterogeneity between case-control studies and the lack of dose-response with duration of and frequency of use, however, do not support a causal interpretation of the association."

Q. And they're referring to the association between talc and ovarian cancer?

A. Yes. But other scientists, you know, such as Penninkilampi, have concluded otherwise,

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that there is, you know, suggestive of a causal association. Health Canada has concluded otherwise, that there's evidence of causal association.

Q. But here we are in 2018, there's a study that's published saying, "Does not support a causal interpretation of the association between talc and ovarian cancer"; correct?

A. Yes. I mean, you know --

Q. Let me just ask you: So scientists disagree about this issue?

A. That's why we are here. If we all agreed, we wouldn't be here.

Q. Okay. Let me move to a different topic.

MR. TISI: How much time do we have? How much time do we have? That's okay. Just write it on a paper.

MR. LOCKE: We're getting close.

Q. Okay. Can we go to Page 62 of your report.

Now, did we already do that? Maybe we already did that. Sorry. I don't want to have to do things again.

A. Please don't.

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THE VIDEOGRAPHER: 6:36.
THE WITNESS: So we have 6 minutes, 36 seconds?
Q. You have 24 minutes.
A. Oh, sorry.
Q. Sorry. We already did that one. So good there.
Let's go to Page 15 of your report. We were talking just a moment ago about regulatory entities and what they found.
In the middle of that paragraph or middle of that page, there's a part that says, "Although the FDA conducted a survey."
Do you see that?
A. Yes.
Q. And they found no asbestos fibers or structures.
But then you, whatever you want to call it, you can call it criticism or deficiencies or disadvantages, you state, "The results were limited, only four out of nine talc suppliers submitted samples, and the number of products tested was low." Is that correct?
A. Well, that is a correct restatement of the facts. So it is not something that I made

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up. I mean, it is true that four out of nine suppliers --
Q. J&J was one of the entities that supplied talc to the FDA; correct?
A. I didn't -- you know -- I didn't -- that FDA document, you know, I'm not aware of who supplied.
Q. You didn't look at it. You criticized, but you didn't look at the fact that J&J submitted talc samples and product to the FDA?
MS. PARFITT: Objection. Misstates his testimony.
A. I reviewed the reference and I reviewed the -- you know, so I'm not testifying I reviewed talcum powder products and ovarian cancer. You know, and I was looking at the evidence. But I didn't look at whether J&J submitted samples or Imerys submitted samples, no.
Q. And you don't know whether, then, the FDA, in fact, tested the two J&J products at issue in this litigation and found no asbestos fibers or structures in the samples?
MS. PARFITT: Objection. Misstates the survey.
A. I don't know -- I don't -- you know, I

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don't know about the specifics, who are manufacturers and -- yeah. But I know the limitations of the survey.
And even they acknowledge that the study could not prove that most or all talc-containing cosmetic products currently marketed are likely to be free. So even despite these -- whoever supplied them and whoever, you know, tested them.
MR. LOCKE: We're almost there. Then I'll turn it back over.
BY MR. LOCKE:
Q. Just one second. If you could go to Page 59, please. Okay.
On Page 59, you've got a Roman numeral X followed by a Roman Numeral III. Do you see that? Talcum powder-induced inflammation. Am I at the right place?
MS. PARFITT: I'm sorry, Tom.
MR. TISI: 59 of the report?
MR. LOCKE: Yeah.
A. It's probably 58.
Q. 58 of the report. Sorry.
MS. PARFITT: No worries.
Q. Okay. So you see that, Roman numeral X, Roman Numeral III?

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A. Have we gone through this? I'll be happy to go through it again.
Q. I want to ask you about something.
A. Sure.
Q. You have a statement, the first sentence says, "Inflammation has long been understood to be an important mechanism underlying the development of ovarian cancer."
Do you see that?
A. Yes.
Q. And then you referenced 61. And if you go to Exhibit 4, that is your list of references; correct?
Well, for me, I was looking at it, because it was broken out separately. But you could see it at the back of Exhibit 10 as well.
A. Yeah.
Q. Do you see that, 61?
A. Yeah.
Q. And if you -- can you read the title of the reference that you're citing to there?
A. The Ness study, is that?
Q. Right. The Ness study.
A. Possible Risk of Ovarian in -- Cancer.
Q. It's "Possible Role of Ovarian

Epithelial Inflammation in Ovarian Cancer."

Now, you're citing that for "long been understood to be an important mechanism," but, in fact, the first word in the title is "possible."

A. Yeah. And you can clarify that. I mean, this is about plausible mechanisms.

Q. But it certainly doesn't say it's long been understood to be an important mechanism.

A. Well, I disagree. I mean, you know, maybe that -- you can't cite all the articles for each statement you make. I wish I did.

But inflammation, as I understand it, is an important mechanism. And at least has been known for a long time about ovarian cancer. And others can opine in more detail. Is that citation the most? Yeah, that particular citation has a possible, you know, clarifier on that.

MR. LOCKE: Okay. Let me just see if I've got anything else here. That's all I have.

THE WITNESS: Thank you.

MR. LOCKE: Thank you. Anyone else?

MS. PARFITT: Let's take a quick break and see if we have any follow-up.

THE VIDEOGRAPHER: Off the record, 5:13 p.m.

(A recess was taken.)

THE VIDEOGRAPHER: Back on the record, 5:26 p.m.

MS. PARFITT: Thank you. Dr. Singh, the plaintiffs have no questions. I want to thank you for your time today.

We would ask that Dr. Singh read and sign.

MR. ZELLERS: Thank you, Doctor.

THE WITNESS: Thank you.

MR. KLATT: Wait. I've got 30 seconds.

THE WITNESS: I want to thank everybody for a very professional, you know -- I've done this a couple of times. And if I have raised my voice, it hasn't been anything personal. It's just been trying to explain something.

MR. ZELLERS: Thank you, Doctor.

THE VIDEOGRAPHER: And we're off the record at 5:27 p.m.

(Deposition concluded at 5:27 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

SONAL SINGH, M.D., M.P.H. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

CERTIFICATE

COMMONWEALTH OF MASSACHUSETTS
SUFFOLK, SS.

I, Janet M. Sambataro, a Registered Merit Reporter and a Notary Public within and for the Commonwealth of Massachusetts do hereby certify:

THAT SONAL SINGH, M.D., M.P.H., the witness whose testimony is hereinbefore set forth, was duly sworn by me and that such testimony is a true and accurate record of my stenotype notes taken in the foregoing matter, to the best of my knowledge, skill and ability; that before completion of the deposition review of the transcript was requested.

I further certify that I am not related to any parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 17th day of January, 2019.

_____
JANET M. SAMBATARO
Notary Public
My Commission Expires:
July 16, 2021

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